Insulin Dependent Diabetes Trust
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Side effects of insulin injections revealed

Julie Botham
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Up to 40,000 Australian diabetics may unwittingly be suffering adverse side effects from taking genetically eng- ineered synthetic insulin, suggests British research completed six years ago which has just been revealed. But the availability of animal-derived alternatives, which doctors agree suit some patients better, is about to be further limited by the withdrawal of the main brand of cattle-derived "beef" insulin from the local market. Novo Nordisk will withdraw from the market in July, citing commercial reasons. "Pork" insulin was withdrawn in 1990, though the firm makes it available to some people on "compassionate grounds".

The UK research, commissioned by the British Diabetics Association, has found up to 10 per cent of diabetes patients may suffer side effects - the most serious of which is a dangerous loss of the ability to recognise they are about to lose consciousness - as a result of taking synthetic "human" insulin. This has almost completely superseded insulins derived from pigs or cows. The research was based on studies of 3,000 diabetics after they switched to human insulin.
Injected daily, insulin replaces a hormone, usually produced by the pancreas, for people whose bodies do not manufacture it naturally. Without it, diabetes is potentially fatal.

The manager of educational services for the NSW branch of Diabetes Australia, Ms Bernadette Lowther, said: "The majority of people have no problems with the transfer to human insulin. For a small minority

we hear reports that the quality of life was impaired..." Supply changes for beef insulin, which is understood to be used by about 3,000 of Australia's more than 400,000 diagnosed diabetics, would affect the elderly the most, Ms Lowther said. Several concerned doctors had contacted the organisation. "This is a significant issue for older people who have controlled their diabetes very well on one injection a day," she said. The tendency was for people to need to inject more frequently - up to four times a day - when they switched to human insulin.

The medical director of Novo Nordisk, Dr John Miller, said there was no evidence that either form of insulin was superior to the other. But human insulin was cheaper and safer to produce as it was guaranteed free of animal viruses. The professor of diabetes at Melbourne's Monash University, Professor Paul Zimmet, said the number of people who genuinely needed animal insulin was "minuscule". However, switching drugs could cause problems because the volume of synthetic insulin required was usually lower, which not all doctors understood.

Mr Ron Walker, 67, of Allawah, says the two years he spent on human insulin were "the most disastrous period of my life". He used the synthetic drug around 1990 when pork insulin was first withdrawn. He lost consciousness several times without warning and eventually insisted on using beef insulin.

Beef insulin will continue to be supplied by Rhone-Poulenc Rorer, which had also planned to leave the market but reversed the decision after renegotiating its price.

When insulin is a curse, not a cure

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Report by Veronique Mistiaen
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One in five diabetics reacts badly to human insulin, but doctors don't always listenIn the early eighties Amanda Sugarman switched from the animal insulin she had used since childhood to a genetically engineered "human" one. The drug had been hailed as a breakthrough and, for most patients, it was. But for Amanda the changeover marked the beginning of seven painful and distressing years. Her experience, shared by thousands of diabetics, raises the question of what doctors should do when scientific evidence and patients' experiences appear to contradict one another.

"I never had any trouble during my years on animal insulin, but with the human one I felt I couldn't control my diabetes," says Amanda, a mother of two from Leeds. Her blood glucose level started to fluctuate wildly. "When it drops you feel tired and nauseous," she says. "When it's high you become bad-tempered and lethargic - a bit like PMT, only twice as bad."
Like Amanda, more than 250,000 people in Britain have type 1 diabetes, necessitating daily injections of insulin to control blood glucose levels. Until the early Eighties insulin was extracted from the pancreas of pigs or cattle. Then scientists introduced the insulin-producing human gene into bacteria or yeast to produce "human" insulin.

By the late Eighties it had become the most common form of treatment in the West and people who had diabetes newly diagnosed were automatically started on it. It looked as if animal insulin would be phased out. For about 80 per cent of diabetics the changeover was a success. But for others the new drug caused problems. Amanda found that she no longer experienced the vital warning symptoms - sweating, shivering and a fast heartbeat - to let her know that her blood glucose level had fallen so low that she was at risk of a hypoglycaemic coma. "Many times at night I went into a coma and my husband had to inject me with glucose to get me out of it. Without warning signs you lose your independence. You have to rely on family and friends to know what to do," she says. Amanda complained to her doctor, but after changing her dose a few times he became impatient as scientific studies show no difference between the two insulins, apart from a slightly faster action in the human one.

Yet, unknown to her, about 3,000 people had written to the British Diabetic Assocation (BDA) describing similar problems, and many letters were accompanied by detailed records of blood-sugar levels. Specialists commissioned by the BDA analysed a sample of nearly 400 letters and concluded that most did have problems with hypos and half experienced the loss of warning signals. This sometimes resulted in accidents, injuries, loss of jobs and disruptive or aggressive behaviour. One fifth of the surveyed patients managed to switch back to animal insulin and almost all reported a great improvement to their health.

The BDA commissioned a review of all clinical trials and other medical evidence to compare the side-effects of animal and human insulins. The report, by the Nuffield Institute for Health in Leeds, completed this spring, concluded that "human insulin doesn't increase the frequency or affect the symptoms of hypoglycaemia among the general population using insulin". But it acknowledges that some people have had problems while using human insulin. The Government's Committee on Safety of Medicines came to a similar conclusion.

For some patients and doctors this chorus of "no evidence" is infuriating. Matthew Kiln, a South London GP specialising in diabetes, says: "The medical establishment doesn't regard what patients say as a valid form of evidence, and that is ludicrous." Medical studies, he says, are done "in hospitals with a highly selected group of people in a situation that doesn't reflect real life, so they may not pick up subtle differences". He is also a diabetic and he tried human insulin. "It was unbearable. I had many hypos. I kept passing out and my personality changed. I became short-tempered. But my doctor wouldn't listen." In desperation, he co-founded the Insulin Dependent Diabetes Trust, a charity that campaigns for a patient's right to information and choice, and to ensure that animal insulin remains available for those who need it.

Many specialists who are not convinced that human insulin is to blame for the problems agree that patients should have a say in their treatment. "With chronic diseases, when patients depend for their lives on medicine, they should be made comfortable with their treatment," says Stephanie Amiel, the Professor of Diabetic Medicine at King's College Hospital, London. "If two treatments are of equal safety and efficacy, they should be able to choose. There is a danger of not looking at other issues that might be causing hypos." She mentions a study where she and colleagues at Guy's Hospital were able to restore warning signals in patients on human insulin.
Other known causes for frequent hypos and loss of warnings include: lots of previous minor hypos, which impairs the ability to recognise the next one; timing of meals; increase in exercise or failure to evaluate when the resulting hypo will take place; and misjudging how much insulin is required.

Mark Airey, a senior research fellow at the Nuffield Institute, says that patients were initially given the same dosage and regimen as they had had on animal insulin. But because human insulin acts a bit faster, the regimen needed readjusting. It is also possible, however, that people who have been on animal insulin for a long time develop antibodies to it, and these slow down insulin action. Longstanding diabetics also develop complications, including neuropathy (nerve damage), so they may not be able to feel the warning signals as well.

However, Dr Kiln believes it is not just people who had used animal insulin who have problems with human insulin. Amanda's daughter, Donna, was put on human insulin at 7 when she had type 1 diabetes diagnosed. She suffered the same wild fluctuations as her mother. "They would call me from school because Donna was becoming violent. She was having hypos, but she didn't know it." When Donna took animal insulin, her symptoms disappeared.

In many countries, such as Australia, Canada, France and Sweden, animal insulin has been withdrawn. In the UK at least one company, CP Pharmaceuticals, has pledged to keep producing animal insulin as long as people need it. Meanwhile, pharmaceutical companies have already developed a new generation of human insulin (analogue insulin), that provides better control and helps diabetics in their juggling

act. The ideal treatment, says Mark Airey, would be an insulin that releases itself according to needs - a wristwatch-like glucose monitor that would constantly give your blood-glucose level and an insulin you could inhale instead of injecting.

Diabetic cleared of murder

BBC News
16 December 1999

A man who stabbed his friend through the heart was allowed to walk free from court today after a judge cleared him of murder because of his diabetes. Medical reports showed that Alasdair, a senior civil servant aged 37and diabetic sine the age of nine, had too much insulin in his body and suffered a three-hour blackout during which he killed Nicholas Trent and attacked police officers.

Mr Trent, 45, died in June this year after being found in a neighbouring garden in Stockwell, south London, where he shared a house with Alasdair. Officers who went to the house in June this year said he "fought like a man possessed" when they tried to arrest him. When Mr Padmore was interviewed by police he said he had no recollection of the incident. "There is little doubt that the defendant was suffering from hypoglycaemia before, during and after the event," said Mr Mark Dennis, prosecuting at the Old Bailey. "He reached a state of hypoglycaemic automation."

Diabetes is a disease which destroys the insulin-producing cells in the pancreas. Sufferers must take insulin to control blood sugar levels, if glucose levels become too low – hypoglycaemia – they can in extreme circumstances suffer from delirium, seizures or loss of consciousness. The condition often appears suddenly and instability and mood swings are among the symptoms. John Coffey, defending, said Mr Padmore was now taking animal insulin instead of human insulin to reduce the chance of him having another attack.

The Recorder of London Justice Micheal Hyam recorded a formal not guilty verdict to the murder charge which the defendant had denied. He said he accepted the medical evidence from Professor Vincent Marks of Surrey University, that his behaviour had been out of control. Outside the court, Detective Chief Inspector Richard Taber said: "The family of the victim has been informed. They are unhappy but understand that the circumstances are unique."

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