Insulin Dependent Diabetes Trust

October 2005 Newsletter

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Headlines

"The Department of Health fully accepts that some people are better suited to animal insulin, and that animal insulin should continue to be made available."

The Rt Hon Jane Kennedy MP, Minister of State for Health
24th July 2005

"There is no overwhelming evidence to prefer one species of insulin over another and patients should not be changed from one species to another without reason."

"Animal, Human and Analogue insulins"
Position Statement, International Diabetes Federation, March 2005

"Genetically modified insulin analogues may provide advantages in patients with problematic hypoglycaemia but they are expensive and there are no long-term safety data."

"Animal, Human and Analogue insulins"
Position Statement, International Diabetes Federation, March 2005

IDDT Goes To Westminster - And This Time Comes Back Smiling!

The Minister's letter

After all the hard work of our members in lobbying for recognition of

the adverse effects that GM insulins and for the continued availability of animal insulins, readers deserve to see that actual letter from the Minister of Health, Jane Kennedy MP on July 24th 2005, so here it is:

From the Minister of State
The Rt Hon Jane Kennezdy MP

Department of Health
Richmond House
79 Whitehall
London
SW1A 2NS

Dear Ms Hirst,

Thank you for coming to meet me at Portcullis House on July 11th, to discuss your concerns about the continuing availability of animal insulin.

May I first of all say that the Department of Health fully accepts that some people are better suited to animal insulin, and that animal insulin should continue to be made available. At this time, neither of the two suppliers of animal insulin to the UK has informed us that it intends to stop supply it, although Novo Nordisk says that it will make a decision in 2006.

We have again sought assurances from Wockhardt that it has no plans to discontinue supply of animal insulins. The company says that animal insulins continue to be key products for it. As part of an investment program in its UK sterile manufacturing facilities, production capacities for such products will be significantly enhanced over the next 6 to 12 months. The company says that this investment is essential in order for it to take full advantage of the commercial opportunities that may present themselves, including in the animal insulin market.

Although the market for animal insulin is relatively small, Wockhardt has recently underlined its commitment in this field by seeking registration of its porcine insulin range in Canada. It is expected that Canadian Marketing Authorisation will be in place before the end of the year, which will mean that patients currently being prescribed animal insulin from Eli Lilly, will have an alternative when this is withdrawn from the market early in 2006. Wockhardt has been working closely with Lilly and Health Canada to ensure that there is continuity of supply for patients who wish to continue taking porcine insulins.

As far as adverse effects of human insulin are concerned, it is current clinical practice to start patients on human insulins and there is no clinical evidence that human insulins cause any more adverse reactions than animal insulins. This view has overwhelming clinical and professional support, and is borne out by the July 2000 Duabetes UK comparative report on all the various animal versus human insulin studies (as the British Diabetic Association).

We have considered whether further (non company) research might be carried out on the adverse effects of human insulin, but given the high demand on R&D budgets for research on subjects of high clinical and policy priority we have concluded that there seems little justification for commissioning research at this time. However you may wish to be aware that there is an ongoing (company-sponsored) study to examine the incidence of serious adverse drug reactions in 4,000 patients receiving the recombinant human insulin insulin analogue determir (brand name Levermir) - the findings from this study will be reviewed by the MHRA.

During our meeting, we discussed how the profile of the issue might be raised, particularly with doctors. As you will be aware, there have been two previous articles on hypoglycaemia unawareness on transferring from animal to human insulin in the MHRA's drug safety bulletin "Current Problems in Pharmacovigilance", the most recent in September 2000. I have asked officials to make arrangements for another article to appear in the near future. I have also asked them to liaise with National Diabetes Support Team (NSDT) on the possibility of including an article on the Yellow Card Scheme on its next briefing and to discuss with Diabetes UK the possibility of inclusion on their website of a link to www.yellow.gov.uk where patients can report suspected ADRs.

Finally, the MHRA is currently taking forward the recommendations of the Independent Review of Access to the Yellow Card Scheme including patient reporting, access to Yellow Card Data and proposals for increasing awareness of the Scheme.

I hope this is helpful.

Yours sincerely

JANE KENNEDY

Just what does this mean to people who need animal insulin?
IDDT has received many letters of thanks and we can't print them all - here are just a few:

- Many thanks for your letter of 28th and for the good news. Congratulations Jenny! Although we may have recently done a little bit to help, it is your persistence over many years which has achieved this result. Thank you very much.
- Congratulations. No one deserves this victory more than you and your team. As long as your organisation exists I will always back and support it. Thank you all for the commitment and hard work you have shown, and I am sure will continue to show as long as IDDT exists.
- Just read the GOOD NEWS! letter Jenny. What an achievement! We're all in need of some positive news and this is a cracker.
- It is great news that the UK Government now accepts that not everyone can use 'human' insulin. I now need to persuade my doctor in Australia that I am not the odd one out!!

But there is one that speaks for all of us:
It is not often that my mail produces tears of joy, but this was the effect of your letter. Thank you for all your hard work so far. The results that you have produced are fantastic. Now I am going to write to my MP and thank him.

The battle for the acknowledgement by the Dept of Health of the adverse effects of GM insulins is won.
This statement stands for the future. Doctors, nurses and the insulin manufacturers may disagree, but the Dept of Health that collects all the evidence, not only accepts, but FULLY accepts that some people are better suited to animal insulin.

The EU Commission response to a petition on this issue states that *"Any form of health care delivery is the remit of the Member States. This includes national provisions for the availability of insulin formulations from animal origin in addition to the dominating genetically-engineered formulations of human insulin for individual treatment."*

In the centre pages of this Newsletter, you will also find a Position Statement by the International Diabetes Federation [IDF] and this entirely supports IDDT's views.

In the light of all these statements, the UK government has no alternative but to make provisions for the ongoing supply of animal insulins. Failing to do so, would make it responsible for the consequences - the decline in health and possible death of people unable to tolerate GM insulins. By making choice available to suit all needs, the government has passed the responsibility to where it belongs - with the prescribers, hopefully in discussion with patients.

Where do we go from here?
We cannot be complacent, there is still a long way to go. We must not let the government 'accidentally forget' their July 2005 statement and we must be aware that if/when Novo Nordisk discontinue pork insulin, there will be only one supplier of animal insulins. So we must be vigilant and ensure that animal insulin supplies are secure for both the short and long-term future.

If we are to support patients in having a truly informed choice of insulin treatment, we also need to ensure doctors and nurses involved in diabetes care are made aware of the new statement from the Dept of Health. Clearly this is best coming from the Dept of Health, something

we are following up, but IDDT will also be taking an active role in increasing awareness.

People who want or need animal insulin now have the support of the Dept of Health and the International Diabetes Federation.

- There is informed *CHOICE* and no one need be 'forced' to use GM insulins.
- They no longer have to prove to their doctors and specialist nurses that there are adverse reactions to GM insulins, this has been done for them!
- With the discontinuation of some of the GM 'human' insulins, people who do not want to use insulin analogues with their unknown long-term safety, have the CHOICE of using pork insulin, the nearest equivalent to the GM 'human' insulin they have been using.

Just a cryptic note from Jenny - I don't wish to sound ungrateful but, after so many years, why now? There's probably a host of reasons but SEE PAGES 11 AND 12!!!!

IDDT News

IDDT Annual Meeting, Birmingham, October 15th 2005 - we can still take bookings for the meeting until Thursday October 13th so if you would like to come, just give us a ring on 01604 622837. Members will have received the Annual Report for 2004 with this Newsletter. If you would like a full copy of the Accounts, please call IDDT on 01604 622837 or e-mail bev@iddtinternational.org

Christmas Cards - to those that have already bought IDDT Christmas cards, many thanks for your help. For those of you that haven't got around to it yet, please do help us to raise some funds - just buying one pack helps us to continue with our work. The cards are £3.00 per pack of 10 plus 50p P&P up to a maximum of £3.00. Give us a ring on 01604 622837.

Hurricane Katrina - as the UK arm of the Australian organisation, Insulin for Life, IDDT responded quickly to the acute shortage of insulin and other diabetes supplies to help the victims of the hurricane that hit the Gulf Coast of the US. This need was later addressed by the US itself. We would again like to thank all those who donate unwanted, in-date insulin to IDDT for humanitarian aid. It is thanks to you that IDDT is able to help people in need wherever they may live. Please keep the supplies coming.

Discontinuation Of Pork Insulin In Canada And America

The expansion of Wockhardt's manufacturing facilities is good news and provides an ongoing source of animal insulins not only in the UK but also in Canada. Why Canada? Because the Canadian Dept of Health, Health Canada, also accepts the adverse effects of GM insulins, stating in 2003: *"There very clearly are Canadians who need animal-sourced insulins to manage their diabetes. We have no doubt about that at all. The current science knowledge does not really enable us to understand why the synthetic insulins or the human insulins do not work as well for some people as do the animal insulins, but clearly that is the case."*

The supplier of pork insulin, Eli Lilly, is discontinuing pork in Canada by April 2006, although supplies may run out sooner. It is hoped that Wockhardt's pork insulin will have been approved before Lilly's pork insulin disappears but in the meantime the Canadians are pressing for Lilly to continue to supply until Wockhardt receives approval.

And in the US???
Again Lilly has announced discontinuation of pork insulin by the end of 2005, again leaving no alternative sources of animal insulin.

The FDA's response to letters from people who cannot tolerate GM insulins is not good:

"Under current regulations, FDA cannot require any manufacturer to make a given product even if it is medically necessary. That is an underlying reason for providing the personal importation option. FDA would, however, work expeditiously with any manufacturer interested in submitting an application. Please feel free to provide this information to companies and Drug Shortage will gladly communicate their interest to the appropriate review team within the agency."

Obviously IDDT has passed this information to Wockhardt UK and we are encouraging people in the US to write with urgency to their political representatives. IDDT has prepared documentation and evidence to help with this and if you would like a copy please e-mail jenny@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS, UK

Personal importation of pork and beef insulin
The Drug Shortage website (http://www.fda.gov/cder/drug/shortages/) does provide information on this discontinuation and on how to obtain it from non-US sources http://www.fda.gov/ora/import/ora_import_program.html through personal importation.

Just a note about Germany???
Following the EU Petition statement our friends in Germany increased the pressure on the German Government. On June 28th, the German Health Ministry issued a press release stating that people with diabetes who are ALLERGIC to GM insulins will be allowed to import pork insulin from the UK or Switzerland without having to meet the high extra costs of importation themselves. It is a step forward but it only covers people who are allergic and not those who have adverse reactions - not the same thing!

Descendants Of Banting And Best Support Our Mission For Insulin Choice!

2006 is the 85th anniversary of the discovery of insulin. It was Frederick Banting who unlocked the mystery of diabetes, a condition known for thousands of years. Working at the University of Toronto in 1921, Fred Banting and Charles Best were able to make a pancreatic extract which had anti diabetic characteristics. Tests on dogs were successful and within months Professor J.J. R. MacLeod provided the lab space and general scientific direction to Banting and Best and put his entire research team to work on the production and purification of insulin. J.B. Collip joined the team and with his technical expertise the four discoverers were able to purify insulin. The first tests were conducted on Leonard Thompson early in 1922. These were a spectacular success and word spread quickly around the world giving immediate hope to many people with diabetes and some patients in a diabetic coma made miraculous recoveries. The demand for insulin became so great that commercial production was taken over by Eli Lilly.

Fred Banting was brought up on farm, the Banting Homestead, purchased by his father in 1891 and he encouraged Fred to find out why some of his cattle were dying and it was here that Fred became familiar with foetal calf pancreas. The Homestead remained in the family until the death of Edward Banting in 1999 who agreed to bequeath the property to the Ontario Historical Society [OHS] with agreement that it the would be preserved and maintained as a legacy for all Canadians. However the OHS allowed the Homestead to fall into disrepair and it now requires major financial investment to restore it. The Banting Family are setting up a Sir Frederick Banting Legacy Foundation with the aim of restoring the Homestead and in the long term hope to turn it into a camp for children with diabetes.

Sir Frederick Banting left a memorable legacy and a place in Canadian history with his discovery of insulin and it is understandable that feelings are running high that his family home could be lost.

With this background, Lilly's withdrawal of animal insulins in Canada particularly angers Canadians with diabetes - this is where insulin was discovered and they are rightly proud of the men who have saved so many lives. But not only did Banting and Best discover insulin, they bequeathed their discovery free to the world so that people no longer died for lack of insulin. Banting and Best could never have imagined the commercialisation that later followed their discovery or that insulin would not be manufactured on Canadian soil or that eventually people would be denied the type of insulin they need simply for profit.

So when Lilly announced the discontinuation of pork insulin in Canada, beef having gone some years earlier, Carol Baker IDDT's Trustee in Canada, made contact with members of the Banting family to ask for their support for the continued availability of animal insulins and this was willingly given.

If you would like more information or would like to help the Banting family you can email info@banting.ca and visit their website www.discoveryofinsulin.com

Novo Nordisk Discontinuation Of Some GM 'Human' Insulins - Your Choices

As most readers know Novo Nordisk is discontinuing its popular synthetic GM human insulins with Actrapid disappearing by the end of 2005. Here are the discontinuations in brief:

- **'human' Monotard and Ultratard** are being discontinued and there is no direct equivalent insulin.
- **Insulatard [human] in pens** is being discontinued and their only other long-acting insulin in a FlexPen is, yes you've guessed, Levemir.
- **Actrapid [human] in pens** is being discontinued and the only other short-acting insulin in a pen is, surprise, surprise, their shorting analogue, NovoRapid.
- **Mixtard 30 [and the others] in pens** is being discontinued and the only other pen is NovoMix 30 - an analogue

So people who want to use a pen will have to change to analogue insulins - NovoRapid and Levemir.

But you do have a choice - see the IDF Position Statement on the centre pages, it supports your choice and provides the information to inform it.
Many people, especially parents of children with diabetes, are rightly concerned about changing to analogue insulins because of their unknown long-term safety and their potential for carcinogenic effects. The IDF Position Statement makes these concerns valid and notes that no benefits have been observed in large trials.

1. Use the same insulins in vials for use with a syringe
2. Pork insulin is clinically equivalent to 'human' insulin and a nearer match than analogue insulin so use the equivalent pork insulins. They are all available in cartridges for use with a pen from Wockhardt UK.

It might also ease your conscience to know that all these options are significantly less costly to the NHS!

Just a thought: it is the high use and preference of pens and the more expensive preloaded pens that is enabling Novo Nordisk to take this action in the UK. Their website states 'almost 3.5million people worldwide use a NovoPen system: this number covers up huge regional differences. In the US for instance, only around 10% of people with diabetes use the pen devices, whereas in Europe as many as 90% use the pens.'

This suggests that the uptake of pens is lower in countries where the cost is not covered by state health services or health insurance. Thus the removal of the GM 'human' insulins in pens is going to hit people in Europe far more than people in the US who are using vials and

syringes. Perhaps there is a message here for people in Europe - yes, the pre-filled pen is great, it's convenient, discreet and preferred by most people but in reality it is only an injection device.

What is really important is treating your diabetes with the insulin that suits you best. Finally believe it or not, some people choose to use a syringe - they're small and have fine needles too, they are not at risk of faults so that the wrong dose is given and you can actually see that the insulin has gone in!

An example information perhaps you don't know!
When considering your choices look at the US advert for NovoMix 30 as [known as NovoLog 70-30 in the US]

Quotes from the advert:

Paediatric use - safety and effectiveness of NovoMix 30 in children has not been established

Geriatric Use - clinical studies of NovoMix 30 did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently than younger people.

Use in pregnant women - it is not known whether NovoMix 30 can cause foetal harm when adminsitered to pregnant women or can affect their reproductive capacity.

Nursing mothers - It is unknown whether NovoMix 30 is excreted in human milk as is 'human' insulin.

Carcinogenicity - in rats at a dose of 200U/Kg/day [32 the normal dose in humans] NovoRapid, the short-acting component of NovovMix 30, increased the incidence of mammary gland tumours in females when compared to untreated controls. The relevance to these findings in humans is not known.

Prominent New Warnings In Arthritis Drug, Celebrex

Members with arthritis may have been following the concerns about Vioxx and other 'block buster' drugs in the same family used to treat arthritis. The serious adverse effects of heart attacks and strokes were first noted with Vioxx which was then removed from the market. In the first US legal case against the manufacturers Merck. £140million was awarded with many cases of litigation pending. Pfizer, the manufacturers of Celebrex, another drug in the same class, has added prominent warnings of possible cardiovascular risks to its the labelling. Pfizer say that the package insert of Celebrex recommends that it is prescribed "at the lowest effective dose for the shortest duration". There has been a sharp decline is sales of Celebrex due to safety concerns.

Parents Part

Services for children in hospital to be reviewed
On August 15th, the Healthcare Commission announced plans to review NHS services children in hospital as well as smokers and drug users. The Chief Executive, Anna Walker said: "Feedback we've had from patients and the public has shown that children's health, public health and issues related to mental health are all areas that need attention."

Fast-acting analogues OK for children in ketoacidosis
Ketoacidosis [DKA] occurs when there is not enough insulin in the body and blood glucose levels rise very high and impurities build up and this becomes a medical emergency. The current treatment for DKA in children is an intravenous drip of insulin of short-acting regular insulin and this may require admission to the intensive care unit.

Research has been carried out in 60 children to compare the fasting-acting analogue, Humalog injected every two hours [reduced to 4 hourly when the blood sugars began to drop] to continuous intravenous regular insulin. Blood glucose levels fell below danger levels within 6hours after treatment began in both groups although acidosis and ketosis resolved more quickly in the continuos insulin group than in the Humalog group. However the researchers say that the Humalog approach promises simplicity and cost savings. [Diabetes Care, Aug 2005]

Teenagers skip injections to lose weight!
A study in Dundee has shown that more than a quarter of teenagers with diabetes take less than a third of the insulin they are prescribed and they admitted reducing their dose because of pressure to stay slim. This was discovered by comparing the number of prescriptions issued by GPs to the number handed over by teenagers to chemists for dispensing.

Professor Andrew Morris, head of diabetic medicine at Dundee University is quoted in the Daily Record as saying that having diabetes as a teenager is tough but to have to take insulin four times a day is difficult. He adds, they know that the insulin they have to take can lead to weight gain and they desperately don't want this to happen. However, he does say that in many ways this is normal behaviour and the important thing is not to be critical or judgmental. For parents who are so concerned about their youngsters, sometimes this is easier said than done but nevertheless, it is an important message for parents and healthcare professionals alike.

Insulin helps to turn glucose into energy but without enough insulin, the body creates energy from burning off fat. Obviously not taking sufficient insulin is putting their health at risk and to try to combat this a pilot scheme has been set up called 'Sweet talk' to remind teenagers to take their insulin by text message. This is offering the young people support and advice and encourages them to take their insulin when needed - it appears to be very popular with them too.

There may be a link between Type 1 and obesity after all!
All too often, the publicity about obesity links it to 'diabetes' without saying which type of diabetes. Although obesity and Type 2 diabetes are linked, Type 1 diabetes has never been linked to obesity but it seems things might be changing. Two studies published in Diabetes Care [Oct 2003] have shown that obesity may make Type 1 diabetes more likely or hasten its start.

One study looked at the medical records of people who were diagnosed under the age of 19 between 1979 and 1999. Only 5.1% of those diagnosed in the 1980s were obese but 24.4% were obese when diagnosed in the 1990s - a big increase in a decade. As rates of obesity and Type 1 diabetes have increased over the last 20-30 years, the researchers suggest that the increase in obesity and Type 1 diabetes may be linked.

The second study looked at whether there is a link between the age of diagnosis and weight based on the theory that the metabolic changes that occur with increased weight speed up the loss of the insulin producing cells. In the study, the medical records of 94 children diagnosed between the ages of 1 and 16 were examined. The results showed that a lower age of diagnosis was linked to being heavier than average for the age. The researchers concluded the age of diagnosis is influenced by weight.

These two studies suggest that obesity may play a role in Type 1 diabetes and that the old view that someone who has just developed diabetes is thin may no longer be the case. The implications of this are that doctors can't assume that overweight children who develop diabetes have Type 2 diabetes and that diagnosing the type of diabetes will become more difficult as obesity rates rise.

61% of parents of children with diabetes use the internet for information
Research at York University spoke to 358 households where one or more of their children had a chronic disease, mainly eczema, asthma and diabetes. They found that parents said the internet was a useful

source of additional information but it did not undermine their faith in health professionals or their children's medicines and rarely led to a change in treatment. They concluded that doctors do not need to be threatened by their patients using the internet because it is not used in isolation but it is added to routine sources of information such as family, friends books and other media.

The researchers also found that people are sensible about what they find out online and there is not necessarily a need for an extensive system of kite marks to guarantee the quality of health information on the internet but people did appreciate having websites recommended by health professionals.

The researchers surveyed 358 households where there was one or more children with eczema, asthma and diabetes and then carried out follow-up interviews with 69 parents and 16 children. The results showed:

- Nearly 80% of the sample had used the internet and 61% of households with a child with diabetes had looked it up on the internet
- Most people had a high degree of trust for health professionals
- The medical treatment was rarely altered as a result of information from the internet
- Most people were cautious about the potential dangers of health information on the internet but were sure that they could tell the difference between valuable information and 'rubbish'

The research also cast doubt on current assumptions about the idea that uneven access to the internet, due to family income, could lead to forms of social inequalities in this information age. Although internet access was greater among better off families, the study found many examples of households from poor backgrounds making highly productive use of the internet and richer households who made little or no use of it.

But you have to smile! The BMA's joint chairman of its IT committee was asked to comment on this research by the BBC and he said, "This ties in perfectly with the BMA's policy of encouraging GPs to encourage patients to get information from the web. Doctors should not be fearful of patients carrying internet printouts. As long as they are happy to take our view of the information, then it is nothing but helpful." So it's OK to look for information but the information is only OK providing you agree with the doctor's interpretation of it!

What The Papers Say

Wrong insulin dose in hospital - the inquest into the death four years ago of a 90year old lady heard that a junior doctor had given her 10 times the amount of insulin she should have received. After her death, it emerged that the doctor had not been shown how to measure insulin and the hospital discovered that two other doctors trained at the same hospital [University College Dublin] were unaware of the correct procedure for administering insulin. A Department of Health spokeswoman said new guidelines would shortly be issued on how to correctly administer insulin. Can't help but comment that the lady died 4 years ago, so no urgency then! [The Irish News, Belfast 27.7.05]

NHS skill swaps - plans to use nurses instead of doctors for key tasks in the NHS are being implemented with little evidence of benefits, according to research by Prof Alan Maynard and Prof Trevor Sheldon at York University. The policy is a key plank in the NHS modernisation programme and means that GPs and hospital doctors will take on more complicated medical problems and junior doctors will be replaced by specialist nurses expert in conditions such as diabetes, heart disease and cancer. One review found that while the outcomes for patients were similar, costs remained the same. Prof Sheldon is quoted as saying "The considerable changes in skill mix?are a large social experiment with significant risks for the patient and taxpayer". [Yorkshire Post, 3.8.05]

Dentist protest as NHS contract is delayed - a new contract for NHS dentists due to come into effect in October is being delayed until April 2006 and 6,000 dentists have written to Health Secretary, Patricia Hewitt calling for action. The dentists are concerned about the future of NHS dental services. About half the 26,000 UK dentists work in the NHS and in many cases, their earnings are much the same as private dentists but private dentists spend more time with their patients, something NHS dentists want to do. NHS dentists see about 50 patients a day whereas private dentists see half that number. [BBC, 4.7.05]

Health groups lose appeal on EU food supplement ban - groups representing the health food industry lost their appeal against the EU Foods Supplement Directive which subsequently came into force on August 1st 2005. The Directive obliges manufacturers to submit all natural remedies, vitamin supplements and mineral plant extracts for approval and inclusion on a list of food supplements. A list has been drawn up of 112 substances passed fit for consumption which includes Vitamin C, calcium and iron. Many popular ones such as selenium yeast, tin, manganese and vitamin K" have been omitted and are subject to 505 separate appeals. Health Secretary, Patricia Hewitt, a user of vitamins and supplements, said that she would continue to press for the lightest touch possible in carrying out the Directive. [The Times 13.7.05]

Necrobiosis - A Rare Condition

Necrobiosis, full name necrobiosis lipoidica diabeticorum, is a skin condition that usually affects the lower legs. It may start as small red spots or raised areas and the centres are often yellowish and may develop open sores that are slow to heal. They are often itchy or painful. Typically there are usually several spots that are affected that turn a brownish colour that fades slowly but is permanent.

Who does it affect?
It is thought to be more common in women and more common in people with diabetes. People with diabetes account for two thirds of all cases and many of the remainder go on to develop diabetes. Having said this, less than 1% of people with diabetes are affected.

Treating necrobiosis
The real problems seem to be ulceration, infection and the stress from the appearance. Ulceration is often as a result of scratching or trauma, though some ulceration may occur anyway. The ulcerations usually heal if properly cared for and drastic measures are not required in most cases.

No particularly good treatment seems to be known and treatment is not a medical necessity except for ulcerations and infections. Steroid creams are the most common first choice treatment and seem more likely to work, especially if covered with an airtight dressing. Cortisone injections can also be used. Other treatments such as aspirin, locally injected steroids and systemic steroids are reported to help sometimes but it is not known which patients will benefit. There are reports of skin grafts but the results do not seem to be cosmetically attractive and it is recommended that surgery should be avoided.

NB Steroid warning: locally injected and systemic steroids raise blood glucose levels and cause problems with diabetic control but steroid creams do not.

Patient experience reported to IDDT: "I have had a positive response to treating my necrobiosis. I have six patches on one leg and one on the other but thanks to the advice given by the Cosmotologist at my local hospital they have faded considerably. In fact two have virtually disappeared, there is just a faint outline at the top of one. The bonus is it is a natural way to treat them."

The International Diabetes Federation

Position Statement 'Animal, human and analogue insulins'
Before reading this article, perhaps you should know a little about the International Diabetes Federation [IDF] or what it says about itself on its website www.idf.org The IDF mission is to promote diabetes care, prevention and a cure worldwide and it has an umbrella organisation of 191 member associations in 151 countries. It is in official relations with the World Health Organization and the Pan American Health Organization. The IDF has 'Corporate Partners' who pay an annual membership fee. There are different categories of membership according to how much money they pay. In the top category, contributors must have made continuous donations of between ?50,000 and ?100,000 for at least 6years - Eli Lilly, Novo Nordisk, Roche and Servier are in this category. Most other companies involved in diabetes are contributors. Many of the world's leading diabetologists are, or have been, involved with the IDF.

IDDT approached the IDF
In view of its mission, IDDT has approached the IDF several times for help in maintaining supplies of animal insulins but we received no help and little sympathy. So it was a surprise to find a Position Statement by the IDF on *'Animal, Human and Analogue insulins'!* My surprise was even greater when I read it - it says all IDDT has known and made public for years. In fact, it could have been written by us!

In order to not give a biased view of the Statement, here is the full version:

IDF - International Diabetes Federation,

POSITION STATEMENT: Animal, Human and Analogue insulins

March 2005
Insulins are now available in different molecular forms, some because of species differences and some by design through molecular engineering. Modern highly purified animal insulins are safe, effective and reasonably reproducible in their actions. Human insulins, prepared usually by genetic engineering, are similar to highly purified pork insulins. Concerns that hypoglycaemia problems are greater with human insulins have not been substantiated by research. There is no overwhelming evidence to prefer one species of insulin over another and patients should not be changed from one species of insulin to another without reason. Genetically modified insulin analogues may provide advantages in patients with problematic hypoglycaemia but they are expensive and there are no long term safety data.

Early animal insulins were effective but had imperfect absorption profiles. There were also concerns about their ability to induce an immune response (immunogenicity), which increased the variability of their action profiles. The highly purified 'mono-component' insulins reduced the immunogenicity, resulting in faster, shorter actions. Disappointingly, the immunogenicity of human insulin is similar to that of highly purified pork insulin, to which it is clinically equivalent.

Highly purified animal insulins are effective agents to treat diabetes. Human insulin is at least as good as highly purified pork insulin. In many parts of the world, beef insulin provides access to a low cost insulin. While their prices remain lower, highly purified pork and to a lesser extent beef insulins are entirely acceptable and there is no reason to convert. Human insulin has the theoretical advantage that it can be synthesized in limitless quantities at relatively low cost.

All insulins have slightly different properties and patients should not be changed from one to another insulin type unless there is a clear advantage. No insulin type will suit every patient and it is important that variety is maintained in order to find the insulin that suits each patient best.

More recently, genetically modified insulins are being introduced in which the human insulin gene is deliberately altered to confer some specific desirable properties, including a more reproducible action profile. Rapidly acting analogues give better post-prandial (after meal) glucose control and contribute less to nocturnal hypoglycaemia than

earlier short acting insulins.

New 'background or basal' insulins have flatter action profiles and are less prone to cause hypoglycaemia in the night. These insulins are more costly and it is important to recognize that they have not delivered overall improvements in glucose control in large studies. They may have different properties from human insulin and animal insulins and are likely to prove most beneficial in intensified therapy, when good control cannot be achieved without problematic hypoglycaemia.

All insulin therapy is associated with the risk of hypoglycaemia, sometimes severe. There is no evidence that this is worse with human rather than animal insulins. Concerns have been raised in some countries that human insulin use was associated with a different and higher risk of hypoglycaemia. The evidence for this has remained anecdotal, despite serious attempts to document it and find a mechanism. Patients with problematic hypoglycaemia need careful monitoring. Their insulin regimen should be prescribed with knowledge of the expected actions of the insulins involved. Insulin regimens should take into account risk factors such as exercise, alcohol ingestion and illness and these should be clear to the patient. Problematic hypoglycaemia can generally be treated effectively without changing insulin species although patient choices should be respected. Despite the lack of scientific evidence, some patients do better on specific insulin types and some older insulins may have individual benefits in some settings.

Conclusion

People with insulin deficient diabetes require adequate and secure supplies of safe and affordable insulins. Genetic engineering, currently used to make human insulin, should be able to deliver this, as its production capacity is theoretically limitless. Animal insulins remain a perfectly acceptable alternative and indeed some patients prefer them.

Newer insulins offer potential advantages but until these are proven to deliver real long-term benefits safely and affordably, it seems appropriate to use them in patients experiencing specific problems that a specific analogue might reasonably be expected to address. IDF believes that this ability to choose is important and should be supported.

My initial reaction was delight!

At last there is an authoritative document that provides patients, doctors and governments with the facts about all the insulins - not the sales jargon but facts so that the choice of insulin treatment is based in evidence and not influence. I am delighted that people need no longer have to prove to their doctors or nurses that animal insulins remain a *'perfectly safe acceptable alternative and indeed some people prefer them'* and that there is *'no overwhelming evidence to prefer one insulin species over another'*. Finally, I am delighted that eventually the experts in the international diabetes community has supported the long-held views of IDDT.

My second reaction was anger!

The date of the Position Statement is March 2005, why wait so long before publishing it? The IDF did not publish it until their 'Corporate Partners', the insulin manufacturers, had removed animal insulins from most countries around the world! Or until their Corporate Partner Novo Nordisk had announced the discontinuation of human insulins in the UK with the recommendation that those affected change to insulin analogues and what does the IDF say about analogues? They *'offer potential advantages but until these are proven to deliver real long-term benefits safely and affordably, it seems appropriate to use them in patients experiencing specific problems'.* They did not issue their Position Statement until it is too late to prevent animal insulin disappearing from many poor countries to be replaced with 'human' and analogue insulins that are unaffordable for many people.

Yes, there's enough here to make me angry but???

Then I look at the damage that has been done - the unnecessary suffering of adverse effects to GM insulin and in some cases, even death. Then there are all the unnecessary changes of insulin people

have gone through simply because the manufacturers claim the newer ones are better.

And there has been damage to the doctor/patient relationship - people who have experienced adverse effects with GM insulns were, and are, all too often not believed by their doctors or nurses and for these people the doctor/nurse/patient relationship has been damaged. But is it further damaged now? Despite there being no evidence to warrant it, GM insulins have been prescribed on the basis that they are the best, indeed we have been told they are the best. But now the IDF experts are telling it as it is - that *'there is no overwhelming evidence to prefer one insulin species over another'.* Patients have been misled and misinformed and this is still the case with the move towards prescribing analogues. Can faith and trust be restored and if so how?

Then I look at the extra financial burden and the waste. If all the above is not enough, we then have to look at the waste of NHS money by the widespread and clearly, often unnecessary use of GM human and analogue insulins over the last 20years and for what benefit to patients? Apparently little, according to the IDF experts. The benefit has been for the drug companies! The UK situation has been repeated in countries around the world so the profits are enormous.

I think we have a right to be angry
It is right and proper that new insulins are developed to enable a greater choice to suit all needs. But this is not what has happened, choice has been reduced by the drug companies' systematic discontinuation of safe and effective but less profitable animal insulins and now GM 'human' insulins are going the same way. This whole sad saga has been a huge gravy train for the last 20years which appears to have done little to improve the lives of people with diabetes. Yes, the job of drug companies is to maximise shareholders' profits and they have succeeded, albeit in a questionable way, but there are many others that have played a role in their success and they should take some responsibility.

So yes, I'm angry that the IDF has taken so long to make their Position Statement but it is powerful and very welcome. It offers people with diabetes and governments the truly informed choice for which they have been waiting and it supports them in making their choice of treatment.

Whatever insulin you are using, the IDF Position Statement is important to you!
For those with internet access here is the link to the IDF Position Statement

http://www.idf.org/home/index.cfm?unode=DD3CF4D6-6BCE-4005-B25C-46A512741E06.

For those without the internet, IDDT will be happy to send you a copy of the IDF Position Statement, just give a call to IDDT on 01604 622837 or write to IDDT, PO Box 294, Northampton, NN1 4XS

News From The Pharmaceutial Industry

Inhaled insulin update - In September 2005, a US Advisory Committee of the FDA recommended that inhaled insulin, Exubera, made by Pfizer be given approval with certain provisos. One is that continued long-term research is carried out until 2019 mainly because of concerns over its effects on lung function especially in people who have lung disease and people who smoke. Reports suggest that Exubera can be used for Type 2 diabetes but it will not replace injected insulin in Type 1 diabetes. There are concerns it will be sufficiently attractive for people with Type 1 to want to use it, despite the information that it is safe and effective being unclear.

The FDA usually follows the advice of its advisory committees but yet again this advisory committee has come under criticism of having conflicts of interest - at least 3 of its 9 members have direct ties to

Pfizer or its product partner and the acting chairman holds stock in Pfizer. We await the FDA's decision and also that of the EU.

Website poll looked at inhaled insulin - totally unscientific, but a poll on a diabetes information website from July 17th to 24th 2005 asked people, *"Would you like to try inhaled insulin?"* The results were as follows:

- About 25% were excited at the chance to try it.
- Over 50% wanted to see more long-term studies.
- 15% were worried about long-term lung damage and are not interested at all.

Levemir receives approval in the US - announced by Novo Nordisk in June 2005. Approval has not yet been given for its use in children as this is still under review by the FDA. It is expected to reach the US market during the next 12 months. In June Levemir had already been approved in 37 countries, including the EU countries but had only been introduced in 11 EU countries, additional launches expected during the second half of 2005.

Roche Diagnostics to reintroduce its insulin pumps in the US - two years ago shortly after Roche, Switzerland, took over the Disetronic pump business they were barred from selling their pumps in the US as they failed an FDA plant inspection. Roche have prepared for another FDA inspection and expect to be back on the market later in 2005.

Remember! Patients Can Now Report Adverse Drug Reactions!

You can now report any suspected adverse reactions you experience, so do use this right. You only have to *suspect*, not prove, that adverse effects are caused by a drug. Adverse drug reactions can occur immediately or days, weeks or even years after taking a medication.

Here's how to report any adverse reactions:

- **If you have access to the internet:**

Go to www.yellowcard.gov.uk and CLICK on submit a Yellow Card report. On this site you can also check the adverse reactions reports already made.

- **If you prefer to use a paper Yellow Card reporting form:**

telephone the MHRA on 0207 084 2000 or e-mail patientreporting@mhra.gsi.gov.uk and ask for a form to be sent through the post.

IDDT believes that a more effective system for monitoring suspected adverse drug will result in greater safety for patients.

Looking After Your Feet

Seamless socks

As we all know, it is important that people with diabetes take care of their feet, especially people with diabetic neuropathy. Neuropathy affecting the feet can result in a loss of sensation and an unawareness of pain so that any damage to the feet can go unnoticed. This in turn can cause irritation and ulceration and so it is important to regularly check your feet. Damage can be caused badly fitting shoes but it is also important to think about socks as those with toe seams can also cause pressure which may result in sores. Research has shown that in socks without seams the pressures in the midfoot region are about the same as the pressures in the toe region but in the socks with a toe seam, pressures in the toe region were nearly 10 times higher than pressures in the midfoot region. The seamed toe socks had much higher pressure readings than the seamless toe socks.

Seamless socks are also useful for people who have arthritis, oedema

[swelling], circulation problems and something as simple as wide feet.

If you cannot find seamless socks in the shops, they can be obtained from FQC Ltd, FREEPOST NAT3328, Eastbourne BN21 3ZW Freephone 0800 634 4181 or e-mail contact@f-q-c.co.uk

Slip-resistant shower 'shoes'
Neuropathy where there is numbness or loss of feeling in the feet can result in slipping and falling in the shower or bath. Slip resistant 'shoes' may help - they are available in various sizes for £7.95 a pair from House of Bath Ltd, Dept 240, Number One, Bartlett Street, Bath BA1 2QT, Tel 0870 24 000 42.

Floating water temperature Alert
Neuropathy affecting the feet or hands with loss of sensation can make judging the temperature of bath water difficult. Lifemax have produced a Floating Water Temperature Alert to help prevent scalding in this situation. It is a waterproof clock set in a plastic disc sitting in a stand that can be pre-programmed to a personal temperature level. It is thrown in the water of the sink or bath and gives a read out of the temperature and flashes when the water is hotter than the pre-set personal maximum. It costs £9.99 and is available from Lifemax, Tel 0870 609 1612 e-mail sales@lifemaxuk.co.uk More information on website www.lifemaxuk.co.uk

Painful Neuropathy and Acupuncture
In a previous Newsletter one of our members reported that acupuncture reduced her symptoms of painful neuropathy. Now research being carried out at Bolton Diabetic Centre [Diab Medicine 22 suppl.2] is looking acupuncture for people with painful neuropathy to try to avoid using drugs that have a high incidence of adverse reactions. Acupuncture is given weekly for 6 weeks and a pain questionnaire used at the beginning and the end of the 6 weeks. So far 86% of people had reduced pain after treatment, 33% are continuing with treatment and 12% have either reduced or stopped their current medication.

New drug for neuropathy
Pfizer has developed a new drug [Lyrica in the US] to treat pain caused by nerve damage [neuropathy] in diabetes or the pain from shingles. Pfizer say that the drugs safety has been established in trials of 9,000 patients and the most common side effects were dizziness, drowsiness, dry mouth, an abnormal fluid build up around the ankles, blurred vision, weight gain and difficulty with concentration. The drug has been approved in the US and is expected to be on the market later this year.

New neuropathy research
A UK study, published in the New England Journal of Medicine in January, involving 1,172 people with Type 1 diabetes suggests that more than good control of blood sugars is necessary to prevent nerve damage. In addition to good control of blood sugars, stopping smoking, watching weight and blood pressure are also important.

Gallstones And Diabetes

There are several factors that can increase the risk of gallstones but people with diabetes are at twice the risk of developing them although the reason for this is not clear. Women over 50 are also more at risk, especially if they have sudden weight loss or take some of the cholesterol lowering drugs.

What factors increase the risk of gallstones?

- Obesity
- Increased oestrogen levels caused by pregnancy, HRT or birth control pills.

What are the symptoms of gallstones?

- a sharp, steady ache in the upper abdomen that usually comes on

after eating and can feel like indigestion
- it can wake you up at night.
- a bloating feeling.
- many with gallstones don't have any symptoms and may never have any.

What are gallstones?
The gallbladder is a small organ below the liver and is connected to the liver and small intestine by ducts. The gallbladder stores and concentrates bile which helps digestion and absorption of fats. When we eat the gallbladder releases bile through a duct into the small intestine to help the body absorb fat.

Gallsones form when substances in the bile, such as cholesterol and bilirubin [the pigment in bile] harden to form particles. They can be very tiny or as large as a golf ball. There are two types of gallstones - 80% are cholesterol stones and 20% are pigment stones. People with diabetes tend to have cholesterol stones.

Why does pain occur?
Gallstones can move especially after a fatty meal and if the gallstones get stuck in the ducts this can cause pain which usually lasts for about 30minutes. If this happens often or for long periods, it is sign that the gallbladder maybe becoming inflamed. If the gallstones get lodged in the ducts for a long tome, it can lead to serious inflammation, infection and damage to the gallbladder, liver or pancreas. The symptoms at this stage are sweating, chills, fever and yellowish colour skin or whites of the eye and immediate medical attention is needed.

What is the treatment?

- Some people only have an attack every now and then and about a third of those that have an attack never have another one. This group pf people are advised to eat a low-fat diet.
- In people who have more frequent attacks with nausea and pain the usual treatment is removal of the gallbladder and this is usually done by laparoscopy. After removal of the gallbladder, the liver sends the bile directly to the small intestine,

How to reduce the risk of gallstones

- maintain a healthy weight
- if you diet to lose weight, don't lose weight too quickly
- avoid fasting diets and those with only a few calories
- if you have any unusual pain, consult your GP as treating gallstones as early as possible reduces the risk of complications.

From Our Own Correspondents

SensoCard Plus - I'd recommend it to anyone
Dear Jenny,

I am visually impaired and I have been using the new SensoCard Plus blood glucose meter for the last few weeks. I have noticed some points that I thought may be of interest to other members. It can take me up to 5 minutes to calibrate the machine and it is rather fiddly, but once the machine is set up, it is very easy to use. I would recommend it to anyone with sight problems

I would just add that I find that when the strip is in the meter and I am putting it towards the blood, I find it much easier if I turn the meter [and strip] upside down. I wonder if anyone else has found this?

Mr A.A
Lincs

It doesn't have to be you - the medication can be at fault
Dear Jenny,

Thank you for listening to my problems with Lantus [glagine] and NovoRapid. When I went to the hospital, I saw a very forward thinking

lady doctor who believed me when I said I was playing by the rules and it wasn't working. She said that the Lantus was not lasting as long as it is supposed to. I am now taking between 18-20 units of Lantus but have knocked off the breakfast and lunch NovoRapid unless necessary and just taking between 3 and 6 units of Novorapid after dinner depending on need and I still take 850mg Metformin after meals. I feel so much better. We also agreed that if necessary I could twiddle about with timings - at the moment I take it at 6am, but if that didn't settle, change it to night time and if that fails, split the dose into am and pm. The doctor did say that she is seeing more and more people for whom Lantus is not having the effect it should do.

I hope this gives other people hope to realise that despite the opinion of some medics that you are an out and out failure in controlling your diabetes - it doesn't have to be you, the medication can be at fault.

H.M.
By e-mail

More awareness of frozen shoulder needed
Dear Jenny,

I have been a diabetic for 45 years. I developed a painful shoulder (left shoulder) in 1990 with the right becoming affected 3 years later. Unfortunately it was not diagnosed as frozen shoulder until 1995, when I started steroid therapy and physio. Treatment has not really been effective, I think because it started too late. I am not complaining just stating a fact. I now appear to have exacerbations and remissions of the pain, and recently it is affecting the area around the shoulder blade and ribs.

I really feel the importance of early recognition and treatment is so important. Another area of concern to me is that this condition does not appear to be recognised in many nursing magazines or texts. I feel most people with IDDM, who also have frozen shoulder, should make this very clear to nursing staff.

H.L.
North West

IDDT advertisement made all the difference
Dear Jenny,

I was diagnosed when 'human' insulin had just come on the market and was never given any choice of treatment - automatically given 'human'. A couple of years ago IDDT placed an advert in our local paper which listed the adverse effects that people have had with 'human' insulin. I had all of them and had never felt well from being put on insulin. My doctors didn't believe me and even when I showed them the advert, they still did not believe me [and were not too polite about IDDT!] I insisted on changing to pork insulin and nearly all my symptoms disappeared but above all my wife said I was a changed man and far easier to live with.

I am delighted to hear that the government and Dept of Health believe those of us that have been through this experience and need animal insulin. Perhaps the bigger job now is to convince our doctors and nurses that just because animal insulin has been used for years, does not mean that it is not an effective insulin for many people and one that works better than the newer ones for some people. I do not want to be ill again and the only way to prevent this for me, is by using pork insulin. If I had not seen your advert, I would still be unwell and experiencing all the adverse reactions so I hope you can get this information to more people with diabetes.

P.L.
South West

Taking Medicines

Ask about Medicines Week - November 7th to 11TH 2005
The aims of the organisation, Ask About Medicines, are to increase people's understanding of their medicines and to help patients to be involved in decisions about their treatment.

The key message for Ask About Medicines Week 2005 is to encourage more people to ask questions of their healthcare professionals about medicines and their other options and to encourage healthcare professionals to welcome this. Asking questions enables people to make better informed choices about taking medicines and if they ask questions about medicines they are more likely to use them safely and effectively.

The key questions for patients to ask are:

WHAT does this medicine do?

WHY is it important that I take this medicine? Are there any other treatment options?

WHEN and how should I take it?

HOW long should I take it for?

WHAT should I be aware of when taking this medicine? (eg, possible risks, side effects, taking medicines with certain foods/drinks/activities, what to do if I don't feel well while I am taking it, etc)

WHERE can I go for more information?

Ask About Medicines receives 56% of its funding from the Dept of Health so it obviously supports this campaign which includes people with diabetes who want to be involved in decisions about their insulin, so don't be afraid of asking questions, you have Dept of Health support!

Taking medicines correctly - is most likely to happen when their benefits are immediately obvious and least likely to take them when the condition is in the future.

Cost to the NHS - the drugs bill for the NHS is in the region of £7bn a year and so whatever the cause and however understandable, not taking medicines properly is a huge waste of NHS funds not to mention the effect on people's health.

Why diabetes patients take or skip medications
A study [Arch of Int Med 29.8.05] has shown that people with diabetes are more likely to take their medications when they trust their physicians and when they are not depressed. Researchers looked at 912 diabetic patients in the US, mainly on low incomes and found that:

- Remembering that this is the US where people pay for their drugs, in those who had monthly drugs costs over $100, nearly 30% who reported little trust in their doctors said they skipped medication because of cost compared with 11% who trusted their doctors.
- People who reported symptoms of depression were twice as likely as those without depression to not take their medication.
- Nearly half of the low trust group reported symptoms of depression compared with 35% of those who trusted their doctor.

The researchers concluded that their study highlighted the need for doctors to establish a trusting partnership with patients, to deal with depression and discuss the effect of medications and low cost options.

Non-adherence to treatment of diabetes
Researchers surveyed people with diabetes living in Antwerp and found that the main reason people with diabetes do not follow treatment advice is poor communication. The patients admitted to having a poor knowledge of their condition but said that they receive incomplete information from their doctor and that doctors often give conflicting information. They also reported that their doctors paid too little attention to their health beliefs and they felt their doctors could

not relate to living with a chronic medical condition. The researchers believe that this non-adherence to treatment is expensive to health services and the way forward is the development of a more open, co-operative relationship between health professionals and people with diabetes. [Pract Diab Int 2003;20:209-214]

Bits And Pieces Of Information

HypoStop had its name changed in August and is now called GlucoGel. 'Formerly known as HypoStop' will remain on the packaging to avoid confusion.

New European Health Insurance Card - from September 1st 2005 a new card will be issued, EHIC, replacing the existing E111 form. Existing E111 forms remain valid until the end of the year. The benefits are the same - entitlement to reduced or free essential medical care while in EU countries and Switzerland.

Talking labels - many people take a variety of prescribed drugs at the same time which often require different dosage, quantity or frequency. This can cause difficulty and the risk of errors for some people, especially those who are visually impaired. Talking labels, about the size of a credit card, attach to standard medicine packages and allow the recording and storing of a 60second message that can be played back by pressing a tactile button. The message can be recorded by the pharmacist with a description of the medicine, dosage instructions and important warning notes. The labels cost £6.95 each and are available from Talking Products Ltd, Tel 01794 516677 e-mail info@TalkingProducts.com More information on website www.talkinptoducts.com

Servre Hypoglycaemia is On The Increase

A cross-sectional survey of severe hypoglycaemia was carried out in people with Type 1 diabetes in a Swedish out-patient clinic in 1984 and then repeated in 1998 [ref1]. The results showed that the frequency of severe hypoglycaemia had increased by 50% over 14 years. Further analysis showed that the only risk factors for severe hypoglycaemia are hypo unawareness [loss of warnings] and HbA1c results. The authors point out that this increase in hypos is despite daily self-monitoring of blood glucose levels and despite more frequent use of multi-daily injections. Surely we expected this as research in 1992 [DCCT] showed that multi-dose regimes and tight control resulted in a threefold increase in severe hypos compared to 'conventional' treatment.

The authors suggest that insulin analogues and pump therapy may reduce the numbers of hypos - 'may' because the evidence for this is pretty thin and they also suggest that the present blood glucose monitoring systems are not sufficiently sensitive to specifically detect hypoglycaemia. But perhaps the most important conclusions from the authors is that as people with a long duration of diabetes are increasingly vulnerable to severe hypos, this should be taken into account when treatment targets are being set. In other words a one-size-fits-all target is not appropriate for everyone. We would add that if this advice is to be followed then it must be remembered that in two people of the same age, say 30, one could have had diabetes 28 years and the other 2 years

Note: they don't mention another possible cause - in 1984 the vast majority of people were using animal insulins but by 1998 most people were using GM human insulins.

It could be the tools not the patient
A 2004 review [ref2] of hypoglycaemia reminds us that hypoglycaemia is caused by insulin treatment and not by diabetes itself. The review also points out that:

- hypoglycaemia can be a barrier to achieving 'good' control because the fear of hypoglycaemia is a major problem so people run their sugars higher.
- injected insulin together with the imperfections in insulin therapies results in blood sugar fluctuations that are greater than they should be. [Good to know that the tools and not the patients are to blame for hypos!]
- it is frequent hypoglycaemia that often causes damage to the counterregulatory hormone system, the hormones released to give hypo warnings. This is why frequent hypos result in loss of hypo warnings and further damage which in turn leads to worsening episodes of severe hypoglycaemia. It is a vicious circle!

This review suggests that approaches to trying to prevent hypos should include:

- Glucose monitoring
- Patient education
- Meal planning
- Medication adjustment [maybe this should include trying animal insulin!]

In people with loss of warnings the suggestions are:

- Total avoidance of hypos may restore warnings [easier said than done]
- Behavioural training focusing on recognising more subtle symptoms may work for some people.

However, the review concludes that the best way to prevent hypos and ultimately loss of warnings is a methodical search for the pattern of when hypos occur and why. If there is a pattern, then maybe there are actions to be taken that will prevent the hypos.

Ref 1 Lakartidningen 2004 Dec 23;101(51-53):4202-5

Ref 2 Treatments in Endocrinology 2004,vol 3:No2: 91-193(13)

Perhaps another cause of increased hypoglycaemia - after meals due to fast-acting analogues, Humalog and NovoRapid

A letter in Diabetic Medicine [ref1], expressed concerns about hypos after meals due to the fast action of Humalog and NovoRapid and the confusion for people with diabetes when hypos occur at an unexpected time. This was followed by another letter from Dr Felix Burden [ref2] who said that he has found another problem. This is that people who are very used to taking insulin 30minutes before their meals may forget their newly taught technique of taking their NovoRaoid or Humalog immediately before meals which can result in them going hypo before their meal.

Dr Burden maintains that the advice for patients must be to reinforce the need to inject WITH food and to test blood glucose levels 1 or 2 hours after eating to assess the risk of hypoglycaemia. He also said the when changing any insulin the standard advice of reducing the dose by about 10% should be adhered to and subsequently increasing their insulin dose if the blood test indicate that it is necessary.

Ref 1 Diab Med 2004;21:297
Ref 2 Diab Med 2004;21:1373

Another Company In India Launches Its Own Brand Of 'Human' Insulin

Biocon Ltd expects to capture about 20% of the country's insulin market in the next 2 to 3 years. India's insulin market is dominated by Lilly and Novo Nordisk. Biocon has registered the new insulin, Insugen, in a few countries with its immediate focus being the Middle East, South East Asia and Latin America. They already have an agreement with US drug company, Bristol-Myers Squibb to supply this DNA insulin in bulk.

Just a thought???..
Rumour also has it that the US and the EU could give approval to generic 'human' insulin, presumably because the patent has now run out, and if this happens the cost would probably come down as the main insulin manufacturers would not be able to dictate price. Is this a reason for Novo Nordisk and Lilly removing their 'human' insulins and heavily marketing their analogue insulins? If they are successful in this, then their market share will not be too affected by an introduction of generic 'human' insulin.

Religious And Vegetarian Grounds For Using GM Insulins Donn't Stack Up

IDDT has received quite a lot of calls from people who are opposed to using animal insulins because of their beliefs - vegetarians not wanting to eat animal products but also from people who don't eat pork or beef for religious reasons. Both are quite understandable and appear to be good reasons for using GM 'human' or analogue insulins but there are some misconceptions here about GM insulins in that they are by no means free of animal products.

Lets take GM 'human' Actrapid as an example. It contains pork pancreas, pork gelatine, beef extract, casein from cows' milk, salmon and avian feathers making it hardly animal product free! [In addition, it is also worth noting that these are all products to which people can be allergic.]

While clearing up misconceptions, it is also worth correcting another one - animals are not bred and killed to produce insulin from their pancreases. Pancreases are a waste product from animals slaughtered for meat and the pancreases are collected and insulin extracted from them.

Yet More On Aspartame And Its Possible Dangers

There has always been much debate about the use of the artificial sweetener, Aspartame also known as Nutrasweet etc. It is used in diet drinks such as Diet Cola, Wrigley's Extra Spearmint chewing gum, sugar-free cough drops. In fact throughout the world it is used in 6,000 diet foods and pharmaceutical products!

Published in the European Journal of Oncology [July 2005], a recent Italian 8-week study of feeding varying amounts of aspartame to rodents, many female rats developed lymphomas or leukaemias and the risk increased with increased doses of aspartame. The researchers recommended an urgent re-examination of aspartame's safety, especially to protect children. This has been taken up by The European Food Safety Authority who have announced that they are to review the evidence as a matter of 'high priority'. It seems that cancer risk can now be added to the other 90 different symptoms that have been related to the use of aspartame in humans!

Is aspartame natural?
It is often claimed to be so but in fact it contains two amino acids that are far from natural - aspartic acid and phenylalanine and it is these substances that could be the cause of many of the adverse effects and the link with leukaemia.

Safe daily intake
The last review of the safety of aspartame took place in 2002 and it was in this review that the Acceptable Daily Intake [ADI] of aspartame was decided. The ADI is the amount that can safely be taken daily without significant health risks and for aspartame it is 40milligrams per kilogram of body weight. Even high levels of intake, consumers are unlikely to exceed this dose as this is a lot of cans of Diet Coke but take a look at many of the food stuffs that you buy and artificial sweeteners are in foods you would never expect!

But there are views that people vary in their ability to consume aspartame with plenty of evidence from people who have had some of the 90 symptoms that when they stop using aspartame the symptoms disappear.

It is hardly surprising that according to the European Report, adults and children from the age of 2 to 65 with diabetes are the highest consumers of food and drinks containing aspartame.

Christmas Is Coming So Just A Reminder About Alcohol!

Alcohol can caused delayed hypos in people with Type 1 diabetes - low blood sugars the day after drinking even modest amounts of alcohol the previous evening. Research carried out at the Royal Bournemouth Hospital [Diabetes Care, July 2005] has shown that alcohol has been implicated in up to one fifth of hospital visits for hypoglycaemia, low blood sugars. The researchers investigated the effect of evening alcohol in 16 people with Type 1 diabetes who had normal hypo warnings and who drank alcohol on a regular basis. The participants were evaluated with continuous blood glucose monitoring on two occasions - after taking orange juice and vodka or just orange juice followed by the same meal and same dose of insulin. They experienced 1.3 episodes of hypoglycaemia per day during the 24hours after the alcoholic drink compared to 0.6 episodes after a non-alcoholic drink. The researchers suggest that this research may encourage people to be more 'proactive' in adjusting their insulin appropriately if they are drinking alcohol.

- **Just a few words of warning:**
-
- Try to learn how alcohol affects you and learn the best ways to cope with it.
- It is always best to drink with a meal and to tell someone you are with that you have diabetes.
- You should not assume that because some drinks contain carbohydrate that this will counteract the hypo risk because it doesn't.
- Low carb alcoholic drinks such as Pils contain more alcohol - so not a good idea!
- The warning signs of hypos can be missed with too many drinks and other people may mistakenly think that you are drunk rather than you are hypo.
- Carry out more blood glucose tests to check for hypos for at least the next 24hours

HbA1c Results Vary - and maybe its not your fault!

The HbA1c blood test is the one that doctors tend to rely on to make a judgement of blood glucose control over the last 6 to 8 weeks and we are advised to aim for a target of 7% or less. It is also widely used in research as an outcome measure [or marker] to test various treatments.

In the absence of any other test, it appears to have become the gold standard means of assessing control over time. But as we have pointed out in several Newsletters, it is not without its problems - the HbA1c does not take into account the number of hypos [low blood sugars] so a 'good' HbA1c could actually mean that a person is having a lot of hypos and this is not good control!

What is the HbA1c test?
Hb stands for haemoglobin, the substance in red blood cells that carries oxygen around the body. Glucose may attach to the haemoglobin in a process called glycation and it is this glucose that the HbA1c test measures. It gives the average blood glucose control for the last 6 to 8 weeks. This test is different from home blood glucose tests which

measure the level of glucose in the blood at any particular time.

But there are problems???

HbA1cs can differ between people with the same average blood glucose tests
People with the same average daily blood glucose tests, say both with tests of 7.00mmols/l, can have different HbA1cs despite exposure to the same amount of blood glucose. This means that the glycation process varies in individuals and some people have high HbA1cs in relation to their average blood glucose measurements while others have low HbA1cs in relation to them. Research is taking place in the US to try to discover how and why this process varies in people.

HbA1cs fluctuate with the time of year
The American Journal of Epidemiology [March 15,2005] published a study that shows that HbA1c levels fluctuate according to the time of year. The study looked at monthly HbA1cs of more than 285,000 US military veterans over two years and found that they are higher in winter, especially in cold climates, rising in the autumn and decreasing in the spring. These seasonal patterns were similar in men and women of all ages and races and in people who used insulin and those who didn't. The author points out that high HbA1cs are probably not related to holiday dietary indiscretions such as over eating at Christmas, but to colder temperatures in winter.

So maybe we don't have to be made to feel quite as guilty about our HbA1cs when they don't always meet the clinic targets!

Snippets

BT have fat controller - BT employs 100,00 people and they believe that 4,000 of them are at risk of health problems due to unhealthy lifestyles. BT is sending nutrition experts into offices to target obese employees to create a fitter workforce and reduce the sick days lost to weight-related illness. This initiative is likely to be followed by other employers.

NHS Trust has beach hut - Suffolk East Primary Care Trust has a £48million deficit and so is considering closing a convalescent hospital. But it also has a £10,000 beach hut for staff to use for £5.00 a day. The PCT reject any criticism of this and say that the hut is an asset for staff and runs at virtually no cost to the Trust. Amazing!

Patients to get pets on the NHS - in a scheme being piloted by Lewisham Primary Care Trust in London, long-term NHS patients are to be offered an alternative prescription to pills - pets. Patients will be given up to £1,000 to buy a pet, which medical experts believe provides a therapeutic effect, will motivate patients to exercise and help ward off depression. The Trust told the BBC that the scheme could save money by promoting better health and reducing hospital admissions - but there are many other options. [The Independent, 9.8.05]

Cold cure - the University of Colorado has found that girls at risk of Type 1 diabetes are less likely to develop the condition if their mothers had colds or certain other infections while pregnant. Scientists think that exposure to bacteria may affect the process preceding diabetes.

Medications in prison - for many years there have been problems for people in prison having access to their insulin [and other self medications] and it is not uncommon that people requiring insulin have to queue up to access their insulin before meals and then walk some distance for their meal. In one prison, High Down prison in Banstead where the Centre for Public Innovation is funding changes, prisoners who pass risk assessments can now be given clear plastic, safe boxes in which to store their medication. This is to ensure that there is less risk of them missing their medication and to prepare them for managing their own healthcare on release. The Prison Officers Association were worried that inmates could melt down the boxes to create weapons but the scheme has been modified to prevent the boxes being removed from cells.

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From Your Editor – Jenny Hirst

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