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Insulin Dependent Diabetes Trust

July 2001 Newsletter

Is Type 1 Diabetes Being Sidelined?

One can hardly fail to notice the great emphasis on Type 2 diabetes and understandably so, because it is increasing by leaps and bounds. Type 2 diabetes is going to be a huge drain on health costs.

For many years Type 2 was the 'Cinderella' of diabetes and received little attention. Indeed, the now famous Type 2 study, the UKPDS, was under threat of not being completed because of lack of funds and a lack of willingness to continue to fund this large study into Type 2 diabetes – it was not seen as a priority! But people with diabetes argued very strongly that those with Type 2 were not getting the attention they deserved and so set about raising the necessary £1million. As Chairman of the then BDA Voluntary Groups Section, I have good reason to remember this, most of it was counted in my dining room by a team of Type 1 volunteers!

The present situation is not new - the incidence of Type 2 diabetes has been rising for years and for as long as I can remember there has always been as many undiagnosed people with Type 2 as those with diagnosed Type 2. But what is different is that now the numbers of people affected are quantified and health systems now function on priorities and cost implications. So Type 2 diabetes has become very important to governments because the predicted costs are extremely high. We must also not forget the role of drug companies who must be rubbing their hands together with glee – the Type 2 'epidemic' provides a huge market for a whole range of drugs from blood glucose-lowering drugs to blood pressure pills, cholesterol-lowering pills and now the anti-obesity drugs. Indeed, this could be part of what is driving the research towards Type 2.

Many of the medical journals are mainly full of Type 2 research, awareness campaigns concentrate on Type 2 diabetes with a great deal of publicity about the 'epidemic of diabetes' and the symptoms to watch out for.

But has the pendulum swung too far the other way and is Type 1 diabetes being sidelined?

This is certainly a comment I hear from many people with Type 1 diabetes. No one wants to see the two types of diabetes in competition with each other nor is it a case of one condition being worse than the other. We all recognise that both Type 1 or Type 2 diabetes are serious conditions. Both are equally important to the people with them but they are very different conditions that are all too often 'lumped together' under the name of diabetes. But it is important that in attempting to deal with the Type 2 epidemic, people with Type 1 are not forgotten or harmed.

A recent TV programme in Australia had a nurse, no less, saying that 'diabetes' was a lifestyle condition caused by overeating and lack of exercise. She didn't in any way qualify this with the type of diabetes and left the watching public with the impression that diabetes per se, is caused by 'overeating and lack of exercise'. With Diabetes Awareness Week about to happen at the time of writing this, even I am confused by the articles in the press that swap between Type 1 and Type 2 as if they are the same condition.

Those of us who live with Type 1 diabetes know only too well how often people think that we are to blame for their diabetes because we 'have eaten too much sugar' – hardly possible if diagnosed at 2 years old! This may not sound very important to people who don't have diabetes but it is to people who do. They already struggle against the public's myths and misconceptions of diabetes, they struggle against discrimination and they strive to live an apparently normal life, even though it isn't. They need greater public awareness and understanding of their Type 1 diabetes. It is important that not only is this not forgotten in the attempts to deal with the rising tide of Type 2 diabetes but that the Type 2 campaigns do not make life more difficult for people with Type 1 diabetes.

The vast numbers of people with Type 2 diabetes make it a priority but it is not entirely about numbers. In drawing up priorities, the decision-makers must also take into account the impact and consequences of Type1 diabetes on the lives of children, young people and adults. Let them also remember that there is actually an epidemic of Type 1 diabetes in children under 5 years old – it has doubled in the last 10 years!

"I think we sometimes forget the impact of that diabetes has on people's lives." [Recent quote from a healthcare professional referring to Type 1 diabetes]

Children and teenagers who grow up with diabetes often have a low self-esteem that can affect every aspect of their lives. They live with the daily routine of testing, injecting and watching their diet and more importantly for them, of being different from their peers. Both adults and children live with the day to day fears of hypos and so do their parents and partners. If this isn't enough, they live with health targets that are almost impossible to achieve and as a result feel guilt, remorse and a weight of responsibility for their future health. If complications occur, the initial reaction is often one of 'I'm paying the penalty for the years I have failed to manage my diabetes'. In a practical way, having Type 1 diabetes may affect their jobs, their ability to get insurance and mortgages and at the other end of the scale, their pensions.

It is frequently said that you can have 40 years healthy life with diabetes. Sounds great and not bad if you are not diagnosed until you are 35, like Steve Redgrave. But if you are diagnosed at the age of 2, then 40 years of complication-free life means that you are actually only 42 years old when the complications develop! Typically Type 2 diabetes does not occur in people before the age of 40.

We only have to look at diabetic retinopathy, just one of the complications that can dramatically affect peoples lives and those of

their families, to show the impact of Type 1 diabetes. Fifteen years from diagnosis approximately 50% of people with Type 1 diabetes will develop proliferative retinopathy and most will show some degree of retinopathy. [ref1] To use a government saying, in real terms, this means half the children diagnosed under the age of 5 will have some degree of retinopathy by the time they are only 20 years old! Fifteen years after diagnosis of Type 2, only 5-10% will develop proliferative retinopathy – in real terms, only up to one tenth of the people with Type 2 diagnosed at 50 will have some degree of retinopathy by the time they are 65.

In Type 2 diabetes cardiovascular disease is the major cause of death when compared to the general population, but it must not be forgotten that cardiovascular disease is also the highest cause of death in Type 1 diabetes. [ref2]

Not only is it important that research continues with vigour into Type 1 diabetes but also that people affected by it, can see that it is being carried out and given as much importance as Type 2 research. Despite the hype about islet cell transplantation, Type 1 cannot be sidelined on the basis that there may be a cure around the corner!

Type 2 diabetes is largely preventable – Type 1 is not!
Clearly Type 2 would be much less costly to treat if resources were directed at screening and prevention rather than treatment, especially in 'at risk' people. But is it possible that a much more aggressive approach to diet for Type 2 would achieve lower blood glucose levels and a reduction in the risk of complications? Would aggressive reduction of carbohydrates, as well as 'bad' fats, be as effective, or even more effective at reducing blood glucose levels? Accepting that there would need to be a greater education and support system and that this may not be achievable for all, there are obvious advantages:

- reduction in the drugs budget
- reduction in the adverse reactions that accompany many of the Type 2 drugs
- psychological advantage for patients because they are treating their condition with diet and not drugs ie I it does not seem like an illness.

It seems that a fairly simple piece of research would answer many of these questions but would also provide an evidence base for treatment decisions and for guidelines for future care.

Note: Merrill Osmond, one of the Osmond brothers, describes his regime for treatment of his Type 2 diabetes in the Daily Express [5.6.01] *"I reluctantly gave up ice cream and cakes….I eat whole grain cereal for breakfast, green salad with oil and vinegar dressing for lunch. I eat a lot of chicken and fish and no fizzy drinks. I feel so much better because I have stabilised my sugar levels and I have lost more than two stones in weight. I try to exercise everyday."*

The major difference between Type 1 and Type 2 diabetes is important - Type 2 is largely preventable and avoidable but Type 1 is not.

We all hope that the guidelines for diabetes care from the National Service Framework to be published this year, will recognise this. If the future health and welfare of everyone with Type 1 and Type 2 diabetes is to be protected and affordable, the NSF guidelines must reflect that different approaches to Type 1 and Type 2 diabetes are essential and both are equally important to the people affected.

Ref 1 Pract Diab Int Jan 2000;Vol17;No1 Suppl

Ref 2 Pulse Feb 3 2001

'Human' And Animal Insulin Compared

The review by Professor Rhys Williams et al, funded by the then British Diabetic Association

Yes, I do keep coming back to this because reviews are important to help patients and doctors make healthcare decisions. We all know of research that says one thing and shortly after, a different study says the opposite but a good quality review gives the wider picture from all the trials into a treatment or drug and helps to reduce bias.

IDDT, and others, were involved in commenting on the protocol for this review although little heed was paid to our comments. [IDDT Newsletter Oct 2000] We were disappointed that the first version of the review did not fulfil all its stated aims. However, we were even more disappointed when two other versions appeared - one version on Diabetes UK's website completely omits the section about deaths associated with 'human' insulin and the other version in Diabetes Medicine, the Diabetes UK journal for professionals [ref1].

I responded to the version in Diabetes Medicine and my letter was accepted. It was not published for 6 months by which time even I had forgotten I'd written it! [ref2]

Jenny's criticisms:

- The aims of the review were to look at hypoglycaemia and other side effects but the 'other side effects' had been excluded from the review so hindering patients' and doctors' abilities to make an informed decisions.
- Many of the intended outcome measures had not been addressed so making it impossible to show whether there are any positive effects of treatment with 'human' insulin compared to animal insulin.
- Even if research is missing or unavailable, this should be reported in a review because it could be vital for decision making by patients and doctors.

I ended by saying that the omissions, changes and failure to address all the adverse reactions to 'human' insulin adds to the mistrust that already exists amongst patients and is misleading to them and their physicians.

The authors' response was published:
They strongly refuted this last statement although they made no mention of why there are 3 versions or why the section about deaths related to 'human' insulin had been removed. They made the following points:

- the original aims did encompass other possible adverse effects and they no way intended to mislead by concentrating on hypoglycaemia but that ***in their view*** this was the issue of most concern.
- there is no reliable data on other adverse reactions.
- the issues surrounding the 'relative efficacies' of 'human' and animal insulins would require a further review and probably more original research.
- the review does take the matter forward because it clearly "points out the value of retaining patients' and physicians choice between 'human' and animal insulin."

So we now know that the authors themselves decided to make the changes because ***'in their view'*** hypoglycaemia was the issue of most concern. If their ***'views'*** could change the stated aims and objectives, was inviting consumers to comment merely paying lip service to consumers and their perspective, that may help to inform the reviewers?

The authors state that there are no reliable data on the adverse reactions, but this is not reason to change the protocol! They should state that searches found no data to that research has not been done in this area showing absence of evidence rather than evidence of absence.

The positive part - the authors have confirmed the need for animal insulins to remain available to offer alternatives to those who cannot use 'human' insulin, for whatever reason.

A final sting in the tail!
Professor Rhys Williams and Dr Mark Airey end their response:

"Having established this, perhaps it is time we all moved on to the many other pressing topics in diabetes research?"

It sounds like I'm getting my knuckles rapped! Well, I'm too old for that! I have no intention of 'moving on' and ignoring the significant numbers of people for whom 'human' insulin causes adverse reactions.

Insulin is the very core of treatment of type1 diabetes affecting millions of people around the world. Yes, we'd like a cure but while we are waiting, what research could be more pressing than establishing that the insulin used to treat millions of people is the best and does the least amount of harm?

Industry will continue to do what it must to maximise its profits, making it clear that this means global discontinuation of animal insulins. People that live with diabetes are at the sharp end of industry's commercial decisions and it does not seem unreasonable to expect physicians and researchers to want to ensure that patients do not suffer as a result of these decisions. If they fail to do this, then can we be expected to have trust in them or their research?

The review has established that animal insulins should remain available. Knowing that this is the opposite of what is actually happening, simply 'moving on' is not an option for those of us that live with diabetes. They are pretty hollow words unless they are followed by action.

Ref 1 Diabetic Med 2000;17:416-432

Ref 2 Diabetic Med 2001;18:165-167

Tongue In Cheek!

But people on metformin will understand! A Quote: "New Flatulence Filter Pad – intestinal gas is natural but often embarrassing. Finally there is a solution – the Flatulence Filter, a super activated carbon/ foam filter concealed in a simple chair cushion…. The Odor Eat'n Foam air treatment system employs a carbon air filter medium to vacuum out the odors that can't be helped."

From the spelling you can tell that this is an American product but the person that sent the details suggested it was designed by someone taking Metformin for Type 2 diabetes and those who do will understand the significance of this!

The UK Must Resist And Learn From The American Experience

By Bruce Beale

For much of my time as a person suffering from diabetes I had the complete assurance that hypoglycaemia was not a problem, that should I suffer from a severe hypoglycaemic reaction my liver would release glycogen and this would bring me round and enable me to take nourishment. With the new insulins this is no longer so.

Hypoglycaemia is now described as 'an extremely dangerous and potentially fatal condition caused by diabetes.' It is experienced by people with both Type 1 and Type 2 Diabetes and it is characterized by a drop in blood sugar to below normal range which when untreated, can cause altered mental status, seizures, coma and, rarely, death. In small children, hypoglycemia can cause damage to a developing brain. In fact hypoglycaemia is a potentially dangerous condition which is less caused by diabetes but more by the types of insulin used to treat it. It is caused more by the pharmaceutical companies than by diabetes.

The pharmaceutical companies are attacking NICE, the UK

organisation set up to examine the efficiency and effectiveness of drugs and they are also campaigning to allow the advertising of drugs to the general public. If we look at the position in the USA we can see how disastrous such a decision would be.

In the USA the pharmaceutical companies spent last year $1.7 billion on TV ads promoting their products and painting themselves as paragons of virtue and compassion. According to Fortune magazine, the pharmaceutical industry was the most profitable in America by far. This profitability, however, came with a human price tag.

In a series of investigative reports that just earned him a Pulitzer Prize, the Los Angeles Times reporter, David Willman, exposed the risks taken with the public's health by drug companies in their frenetic drive for ever-higher profits. He uncovered documents that reveal how Warner-Lambert, which produced the now-banned diabetes drug Rezulin, willfully ignored evidence of the drug's life-threatening liver toxicity, and even managed to get senior Food and Drug Administration [FDA] officials to disregard the warnings of their own medical experts. This collusion between the pharmaceutical industry, the FDA and the Congressional Oversight Committee - which more often resembles the Congressional Turn-a-Blind-Eye Committee- is becoming deadly. Literally, nine drugs have been pulled off the market for safety reasons in the past four years after causing more than a thousand deaths and countless serious injuries.

And according to drug safety expert Thomas Moore, these numbers only scratch the surface of the suffering. "I believe the number of people injured by these drugs, is grossly underestimated because only a small fraction of cases are reported. We have a flawed system that gives drug companies the benefit of the doubt, and as a result, thousands of people are dying."

This lack of real government oversight is compounded by the industry's aggressive marketing tactics -- which make it seem like these powerful drugs are just like any other consumer product.

But it's a misperception with lethal side effects. Just as Hollywood knows how to make a blockbuster movie "open big," the pharmaceutical companies have learned how to build interest in their latest blockbuster drug. As a result, new, relatively untested drugs are being sampled by millions of people soon after they are approved, so when something goes wrong, the fallout is widespread.

A particularly loathsome example of this involves Duract, a painkiller that research proved could damage the liver. But under pressure from Wyeth-Ayers, Duract's manufacturer, the FDA approved the drug anyway, with a warning to physicians about its toxicity. The drug company wasn't about to let a little thing like fatal liver damage get in its way. It pushed the flawed drug so effectively that more than 2.5 million prescriptions were written in the 10 months before Duract started racking up liver-related deaths and was yanked off pharmacy shelves. As they say in that other kind of drug ad, "Speed Kills."

But bamboozling the American public on the way to massive profits only earns you a slap on the wrist. Glaxo Wellcome was reprimanded a remarkable 14 times for misleading consumers about its asthma drugs Flovent and Flonase. You'd think they'd have got the message after rebuke No. 4, or 9, or 12. And the FDA recently wagged its finger -- for the third time in 14 months - at Pfizer and Pharmacia for running deceptive TV spots touting Celebrex, their jointly marketed arthritis drug.

It's now abundantly clear that the decision to allow drug companies to inundate consumers in the USA with ads for prescription drugs was a serious mistake. It should be reversed, but that's easier said than done. The industry has covered its legislative flank by making extremely generous contributions to elected politicians on both sides of the aisle - more than $18.6 million during the last campaign alone.

We in the UK have to guard against the pharmaceutical companies gaining even greater power. As consumers we need to support NICE and ensure that advertising on TV and the Press is not allowed. Severe restrictions on advertising to doctors and health professionals

need to be introduced in this country.

It is the IDDT alone that has brought the disadvantages of the new insulins to the attention of people with diabetes and those of us suffering from the condition must be grateful to the Trust.

I Just Came Across...

I read an interesting article by a police officer, Tim Savage, about how oficialdom has done more to restrict him than his diabetes in 'Diabetes Breakthrough', the UK Newsletter of the Juvenile Diabetes Research Fund. In the middle of the article he said that he came top in a fitness test, *"which was to hold me in good stead for the problems I was about to run into. In 1987 I went on human insulin and lost all my warning signs of low blood sugar. As you can imagine this caused a lot of problems but my colleagues stuck by me and helped me through it until I returned to my old pork insulin."*

It just keeps on cropping up!

UK Cochrane Collaboration Meeting

March 2001

Report by Jenny Hirst

The Cochrane Collaboration has been discussed in previous Newsletters because IDDT acts as consumers in the Diabetes and Endocrinology Group based in Germany, and within the Consumer Network.

What is the Cochrane Collaboration?
It is an international non-profit organisation that aims to help people make informed decisions about health care by reviewing and promoting the best available evidence on the effects of interventions and treatments. The Collaboration also aims to affect the future research agenda in health, by identifying where enough research has been done, and where more is needed.

So what does all this mean for us as patients or consumers?
We are all aware that some health care treatments make you better but some don't and sometimes the treatment can be even worse than the disease. Sometimes it seems as though a drug or treatment worked because you got better, but really the benefit came from something else, such as a couple of days in bed or maybe you would have just got better anyway.

So we need good evidence from research to know the effects of a treatment in order to decide whether we should try it. This not only applies to us, as patients, but also to doctors who need to base their prescribing and treatment on good evidence, and to decision-making bodies, such as the NHS, who need to base funding decisions on good evidence.

How is this good evidence acquired?
It is certainly not any good just looking at one or two studies, however good they may be. Individual studies are often carried out on specific groups of people or on small numbers and therefore the results cannot be extended to assume that the effects of the treatment will be the same for everyone with a condition under investigation. [One of the problems with the early 'human' insulin trials!] In addition, publication bias creeps in because a great deal of good research is not published and so we are not receiving the complete picture. This is why systematic reviews of all the available research are so important – they give a much more complete picture.

There are Cochrane Groups that cover many conditions, diabetes being one, but others include asthma, heart, stroke, eyes, bedwetting,

injury, depression and many more. The Groups carry out systematic reviews of high quality research and this means the reviewers search for all the studies on a particular treatment – those published in the thousands of medical journals and also any unpublished studies. They then sort out which are the good quality studies and draw conclusions about the effects of the treatment under investigation. The completed reviews are made available, as are abstracts and often a consumer summary – the conclusions written in ordinary language!

But what are good quality studies?
The best ones are those called randomised controlled trials [RCTs] where some people are given a treatment and some are not or they may be given the best established treatment [you couldn't not treat people who require insulin]. Where possible, the trials are carried out in such a way that neither the researchers nor the patients know which treatment they are receiving. The experiences of the people in the trials are then compared and in this way it is more than likely that any differences in outcomes are because of the treatment. From this, the reviewers draw conclusions that provide the evidence of whether or not a treatment is effective. A review can also show that there is no evidence to support a particular treatment or that little or no good quality research has been carried out into a particular treatment or drug. This is just as important for us to know because the use or prescribing of that treatment or drug is not based on proven benefit from research. As more studies are carried out reviews are updated and revised.

I attended the UK Cochrane Collaboration meetings in Oxford for several years and I have watched them grow under the leadership of Sir Iain Chalmers. I was very encouraged by the vast increase in the numbers of reviews that have been done and by the obvious enthusiasm of the people who were carrying out reviews with great enthusiasm for the principles of acquiring evidence to inform healthcare decisions. There were also other people there – consumers/patients, ordinary people like me and the really good thing is that consumers are not treated as 'lesser beings' but are valued as part of the whole process.

However, what is striking every time I attend a UK Cochrane meeting, is the total absence of anyone involved in diabetes. IDDT is always the only consumer involved in diabetes at the meetings but arguably even worse, is the lack of researchers involved in diabetes at the meetings.

This must be of concern to those of us at the receiving end of treatment for diabetes.

- Are researchers in diabetes in the UK not interested in our treatment being evidence based?
- Are they quite happy to assume that the results of one or two studies provide sufficient evidence to treat all people with diabetes without looking for a more complete picture?
- Are UK funders of diabetes research quite happy to spend lots of money on individual studies without realising that these does not provide the best evidence for healthcare decisions?
- Do the consumers that fund research not want to ensure that their money is being spent wisely??

For those of you that listen to Terry Wogan in the mornings, he frequently uses the expression 'Is it me?' I feel rather like this after I've been to a Cochrane meeting!

Is it me? Have I got it wrong? Reviewing ALL the evidence seems to me to be the only way to inform us, the patients, to inform our doctors that treat us and to inform NHS decision makers. So why is there such a lack of enthusiasm in the UK for evidence based treatment of diabetes?

Is the reason that the pharmaceutical industry funds large amounts of diabetes research and other aspects of diabetes [commonly referred to as 'diabusiness' by the cynics!] and perhaps it is not necessarily in their interests to have diabetes treatment that is based on evidence from systematic reviews?

So is it me and have I got it wrong? I can't think so because if I have, so

have all the people involved in the Cochrane Collaboration throughout the world and they're a great deal brighter me! So I conclude that there is something odd about this lack of desire for evidence-based treatment of diabetes but, more importantly, this lack results in our treatment and care not necessarily being the best proven treatment. This must, or should concern, the whole of the diabetes community, patients, carers, doctors, nurses, dietitians, researchers and decision-makers.

Note: I cannot help but make the comment that if a Cochrane systematic review had been carried out to compare 'human' and animal insulins, the treatment of those requiring insulin may well have been very different. A review may well have shown that there is a marked lack of methodologically good studies in this area, and this is valuable evidence in itself.

In the next Newsletter we will be giving summaries of some of the reviews carried out by the Cochrane Review Groups

Avandia [rosiglitazone]

The death of a man from liver failure, may have been connected to the new drug Avandia.

Readers will recall that IDDT provided information about this new drug for Type 2 diabetes in our October 2000 and January 2001 Newsletters. Just to remind you:

Avandia belongs to the family of drugs called thiazolidinediones that includes

troglitazone [Rezulin], withdrawn from the UK market after only 6 weeks because it was shown to cause liver failure in the US. Eventually, the FDA in the US admitted that Rezulin had been responsible for around 90 deaths from liver failure before they withdrew it. Avandia was also granted fast track approval by the FDA and said to be far less toxic than its predecessor. But it is understandable that we should have some concerns about Avandia.

Recently the Torbay Herald Express reported the inquest into the death of Donald Goold, whose diabetes was not well controlled with conventional tablets so he was prescribed Avandia. Mr Goold's liver function tests prior to taking Avandia were described as 'well within normal limits'. A short time after starting Avandia, his health deteriorated rapidly and he was admitted to hospital where his liver function was 'severely disturbed'. At this point the GP reported this suspected adverse reaction to the Medicines Control Agency [MCA] because 'it rang bells'. Mr Goold's liver function continued to deteriorate and he died. The hospital consultant involved, said that in his view liver function tests should be carried out very quickly after starting treatment with Avandia. The coroner stated that Avandia probably contributed to the death but that it appeared to be a one-off case.

This may be the case but it is not very reassuring for patients or for prescribing doctors. It is not sufficient that a drug is simply effective in controlling blood glucose levels – we need evidence of safety and of benefit compared to the existing drugs for the treatment of type 2 diabetes.

But what have we got?

- NICE [National Institute for Clinical Excellence] says that Avandia should not be used in patients with heart failure, liver failure or severe renal insufficiency. They also say that there is no direct evidence from comparative trials that adding Avandia to metformin or to sulphonylurea is any more or less effective at improving control than moving to a metformin plus sulphonylurea combination.
- In October 2000, the FDA warned the manufacturers, GlaxoSmithKline, that they were 'seriously concerned' that some of their advertising materials for Avandia had 'minimised the

precautions' regarding liver damage and that the adverts 'suggest that Avandia is more effective than has been demonstrated by substantial evidence'.

- ACTOS [pioglitazone] is a drug in the same family made by Eli Lilly and Takeda, available in the US since August 1999 and approved and launched in the UK in November 2000. Takeda has now joined the Japanese Health Ministry in warning that Actos may be linked to heart failure but the decision whether to prescribe ACTOS is up to individual doctors. A warning has been attached to its packaging cautioning that it should not be used for patients with liver problems. Takeda said that in the US there have been about 40 reports of possible side effects among Actos users since sales began.

The big question is where is the evidence that this class of drugs has any benefits over existing treatments and if there are any benefits they must outweigh the risks of liver damage/failure. We also need to ask whether fast track approval is in the best interests of patients. Where people are dying because there is no drug available, then fast tracking approval for 'experimental' drugs is understandable and acceptable. But what advantages are there for patients in fast tracking approvals of new, not exactly essential, drugs such as the thiazolidinediones?

But We Have To Have A Wry Smile!

Despite our own concerns about Avandia and this class of drugs, it is hard not to have a wry smile when reading a letter from Tony Bragg, Novo Nordisk Ltd, in the Lancet [Vol 357 May 5th 2001].

He points out that NICE states that there is no evidence that the addition of rosiglitazone is any more, or less effective, than the older drug combinations or starting insulin treatment. But Dr Bragg does add that there is much evidence on the use of insulin. He maintains that the NICE guidelines have led to misunderstanding and confusion amongst clinicians and suggests that NICE amend the guidelines to avoid compromising the care of patients through inappropriate treatment. The guidelines don't seem too confusing to me and I'm not a doctor, but they do mean that thought and care has to be applied before Avandia is prescribed.

Somewhat tongue in cheek, I wonder why Dr Bragg is suggesting that the treatment is inappropriate? The MCA has approved rosiglitazone as a safe and effective drug. The manufacturers have covered themselves by recommending liver function tests before and after it is prescribed. There may be no evidence to show that it is any more effective than existing treatments but there is no evidence to show that it isn't, so why is it inappropriate to use it? Many patients may prefer tablets to insulin injections – perhaps this is why it is inappropriate! Hence my wry smile!

But this is dangerous ground for Novo Nordisk! Imagine what could have happened if NICE had existed 20 years ago when they introduced 'human' insulin.

- No evidence that 'human' was any more, or any less, effective than the existing insulins - like Avandia.
- It would increase the total annual NHS budget - like Avandia.
- Evidence that it caused adverse effects, more than existing insulins - like Avandia.

So would 'human' insulin have received approval from NICE? They may well have concluded that 'human' insulin could be prescribed for those people whose blood glucose levels could not be controlled with existing, proven animal insulins and the increased costs of 'human' insulin to the NHS could not be justified – like Avandia!

Hoilday Tips

The holiday season is upon us and probably after this year's awful weather more people will be leaving the UK for guaranteed sunshine. Here are just a few reminders for your holiday:

- Always take enough insulin, tablets and blood testing equipment with you.
- If you are flying, always carry insulin in your hand luggage and if you have a travelling companion, then split your supplies between you in case one bag gets lost.
- Always ensure that you have insurance that covers pre-existing illnesses ie your diabetes.
- Be aware of the change in time zones and be prepared to adjust your insulin dose to cope with this. Your Diabetes Specialist Nurse will be able to help you with this.
- Always take extra food for the journey. Delays are possible whether flying or travelling on our motorways at home.
- Keep your insulin cool. You can use a Frio Wallet as described in IDDT's Spring Newsletter, available from FRIO UK, Freepost SWC 0667, Haverfordwest, SA62 5ZZ or a cool box will do the job.
- If you develop a tummy bug, you should NEVER stop taking your insulin although it may be necessary to reduce the dose if your blood sugars are low. Drink plenty of fluids to prevent dehydration - bottled water is best. If you can't keep fluids down then call a doctor.
- Remember that hot weather can make your insulin work more efficiently and so there is a greater risk of hypos. If necessary reduce your insulin dose to cope with this.

'Health Advice for Travellers' is a booklet produced by the Dept of Health that contains a mountain of useful information, warnings and precautions about travelling abroad. Especially useful are the details about how to obtain emergency medical care in other countries. This varies greatly according to the country you are visiting, some have reciprocal healthcare arrangements and some do not. For visits to European Community countries, free or reduced cost emergency treatment is available on the production of a valid Form E111. This form is contained in the booklet and must be filled in and stamped by at a Post Office in the UK before you travel.

It is worth remembering that the form E111 only entitles you to state provided emergency treatment to the level that the residents of the country you are visiting receive. This may not be sufficient or cover all the things we are used to in the UK. It is not a replacement for good travel insurance.

'Health Advice for Travellers' is free and can be obtained by telephoning the Health Literature line on 0800 555777.

Diabetic Holiday Foot Syndrome

Research [ref1] has shown that there is a greater risk of foot ulceration that can lead to serious complications, during holidays and especially those taken in hot countries., hence the name 'Diabetic holiday foot syndrome'. Among 435 people studied 17 experienced foot lesions during foreign holidays, 10 of whom reported a foot lesion for the first time. The people with holiday foot damage were a younger age, mainly male and their diabetes was of shorter duration than foot lesions of other origins.

The causes of diabetic holiday foot syndrome were:

- direct injury
- unaccustomed exercise
- walking barefoot on the beach or in the sea
- burns from walking barefoot on hot pavements
- wearing inappropriate inflexible bathing shoes.

If you need further warnings for your holidays, nine out of the 17 people had to be hospitalised for infections as a result of the foot

damage and the average stay in hospital was 11 days.

The researchers conclude that there is a need to increase education about foot care at holiday periods and that this should include preventative measures for those people at high risk of foot lesions.

You Should Know...

- That despite major steps in the understanding of diabetic foot disease [neuropathy], there is no consistent reduction in the rates of amputations among diabetic patients in Western countries.
- Footwear is probably one of the major reasons for the lack of progress in reducing foot ulceration and amputation rates.
- Many studies have shown that there are reduced rates of foot ulceration with multiple treatments which include therapeutic footwear.
- Where therapeutic footwear is prescribed, many patients do not wear these shoes. A study in the UK showed that only 22% of people prescribed special shoes free of charge, regularly wore them.
- Only 3% of 2,348 randomised controlled trials of diabetes management identified by the Cochrane Diabetes Group, were concerned with the diabetic foot and few studies have concentrated on footwear only.

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So while both people with diabetes and physicians are aware of the importance of footcare, perhaps we are all guilty of not paying enough attention our feet.

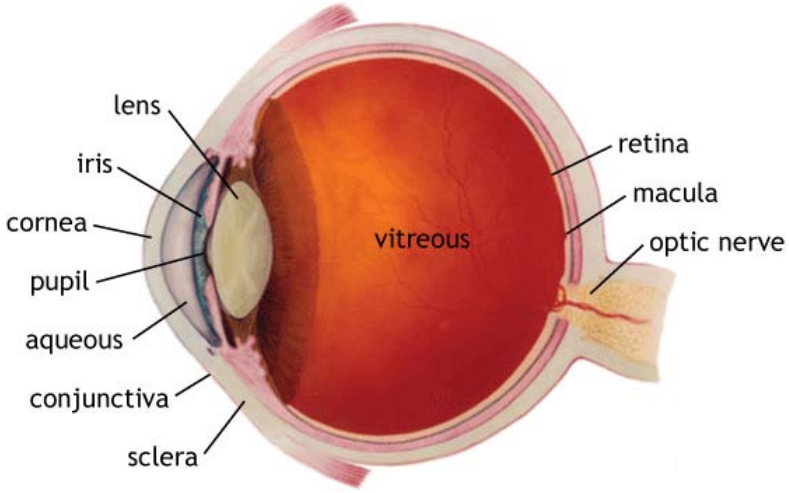
Note: If you have access to the internet, there is good advice about looking after your feet on www.feetforlife.org

Glaycoma

- Glaucoma is a leading cause of blindness
- Glaucoma rarely affects people under the age of forty.
- In the UK it affects 2% of people over the age of forty.
- There is an estimated 250,000 people in the UK with the condition and it is estimated that only half of the people with glaucoma have been detected.
- Glaucoma is responsible for 13% of those on the blind register in the UK.

Facts

- Blindness is preventable if glaucoma is diagnosed and treated early enough.
- Glaucoma is not catching and is not caused by diet, work or any other factors.
- Glaucoma can be controlled with treatment but not cured.
- Glaucoma cannot be prevented but having regular eye checks will enable early diagnosis and treatment and this applies particularly to the above categories. In the UK sight tests are free for people with diabetes and for certain blood relatives of people with glaucoma – parents, offspring and siblings of the person affected.



Before considering glaucoma we need to understand a little of the anatomy of the eye and how the eye works.

- **IRIS** - this regulates the amount of light that enters the eye. It is the coloured part of the eye across the front of the lens. Light enters through a central opening called the pupil.
- **PUPIL** – is the circular opening in the centre of the iris through which light passes. The iris controls dilation and constriction of the pupil.
- **CORNEA** - is the clear circular part of the front of the eyeball. It refracts the light entering the eye on to the lens, which then focuses it on to the retina. The cornea is extremely sensitive to pain.
- **LENS** - is a transparent crystalline structure behind the pupil of the eye. It helps to refract incoming light and focus it on to the retina. A cataract is when the lens becomes cloudy, and then the lens can be removed and replaced with a plastic intra-ocular lens.
- **VITREOUS** – is a clear jelly-like material in the middle of the eye.
- **RETINA** - is a light sensitive layer that lines the interior of the eye. It is made up of light sensitive cells known as rods and cones. The rods are necessary for seeing in dim light. And the cones best in bright light and are essential for receiving a sharp accurate image. Cones can also distinguish colours. The retina works much in the same way as film in a camera.
- **MACULA** - Is the yellow spot on the retina at the back of the eye and is the area with the greatest concentration of cone cells. It is the area of greatest acuity of vision such as reading.
- **OPTIC DISK** - is the visible portion of the optic nerve on the retina. The optic disk is the start of the optic nerve where messages from cone and rod cells leave the eye and pass along nerve fibres and so transfer all the visual information to the brain. The optic disk is also known as the ‘blind spot’.

How we see

For sight to take place light must be able to pass to the retina at the back of the eye. The light passes through cornea and enters the eye through the pupil. It then passes through the lens and the vitreous to be focussed on the retina. The focussed light or images of what we have been looking at, are then passed down the optic nerve to the brain.

What Is Glaucoma?

Glaucoma is a condition where there is loss of vision due to damage to the optic nerve that carries the images from the retina to the brain. Usually glaucoma is accompanied by an increased pressure in the eye, but not always. This pressure is called the intra-ocular pressure or IOP. It is this pressure that damages the optic nerve.

There are different types of glaucoma:

Chronic open angle glaucoma – this is most common form of glaucoma. It produces no symptoms - no pain or redness of the eye and the eyesight seems unchanged. It usually affects both eyes and develops slowly so that the loss of sight is gradual.

The whole of the contents of the eyeball are nourished by a fluid, called the aqueous humour. This fluid circulates within the eyeball and leaves the eye by small drainage tubes at the front. If there is an obstruction within this system, then the fluid cannot escape and pressure builds up within the eye. It is this persistent increased pressure that may damage the optic nerve and cause vision loss.

Acute angle glaucoma – is where there is a sudden increase in the pressure [IOP]in one eye. The eye becomes red and painful often accompanied by misty vision and seeing haloes around lights.

Secondary glaucoma – this is a group of conditions where the IOP is raised and this is caused by other diseases of the eye.

Congenital glaucoma – is where glaucoma is present at birth.
NB. Eye pressure is not the same as blood pressure and the aqueous is not the same as tears.

The following information applies to chronic open angle glaucoma

only – the most common form.

Who May Develop Glaucoma?

- People of Afro-Caribbean origin are between 5 and 8 times more likely to have glaucoma and it may come on earlier and be more severe.
- People with a family history of glaucoma are more at risk. There is a 6 times greater risk if a near relative has it.
- People who are very short sighted [myopic] are more at risk.

NB. It has been thought that people with diabetes are more susceptible to glaucoma. However, recent research suggests that the higher incidence of glaucoma in people with diabetes is more likely to be due to a greater detection rate because people with diabetes often have more frequent regular eye checks than the general population.

Tests For Glaucoma

- *At a high street optometrist/optician*

There are 3 tests that should be done to but not all optometrists do all three tests, so check when you make your appointment. The 3 tests are:

1. To look at the back of the eye and the optic nerve with a bright light [ophthalmoscope]
2. Measurement of the pressure [often called the puffer test]. A raised pressure at this stage does not necessarily mean you have glaucoma.
3. Field of vision test where you are asked to look at a screen with a series of spots of light and you will be asked which ones you can see.

If there are any abnormalities then the optometrist will refer you to your GP for referral to the hospital.

- At the hospital

The following tests will take place at your hospital visit:

Measurement of the intra-ocular pressure - the eye is numbed by a drop of anaesthetic and the eye observed through an instrument called a slit lamp. The cornea [the front of the eye] is lightly touched with an instrument that measures the pressure.

One or more of the following tests will also be carried out:

Gonioscopy – this allows the doctor to observe the angle between the iris and the cornea.

Visual field measurement – you sit at a screen and keep your gaze fixed on a central light. Other lights flash on and off and you press a button when you see them. This tests detects any blind areas of your visual field indicating where the nerve damage has occurred.

Optic nerve assessment – drops are put in the eye to dilate the pupil so that the doctor can examine the back of the eye more fully to record the health of the optic nerve by the appearance of the optic disk. Retinal photographs may also be taken so that these can be kept in your records to establish any changes in the future.

NB. You should NEVER drive yourself to the hospital because the drops used to dilate your pupils leave the vision blurry for a few hours.

Treatment

Eyedrops
The aim of treatment is to lower the intra-ocular pressure and prevent further vision loss. Most people with glaucoma require life-long treatment, usually with eye drops.

Surgery
In some cases the intra-ocular pressure can be reduced by opening up the draining channels with laser treatment or by surgery to make a small drainage hole at the top of the eyeball. In these cases the need for ongoing treatment may be removed but not all cases are suitable and the majority of people with glaucoma need eye drops for the rest of their lives.

Tablets
In some cases tablets may be given to reduce the amount of aqueous produced. Initially these tablets increase the amount of urine passed.

Glaucoma And Exercise
The Medical Director of the Glaucoma Foundation in the US says that there is research that shows that frequent activity such as swimming or brisk walking can lower the pressure within the eye. But he warns against sports that involve turning upside down – certain yoga positions and scuba diving, can raise the pressure. [Reported in Health Which? December 2000]

Driving And Glaucoma
If glaucoma is diagnosed then you should inform the DVLA in Swansea and your motor insurers. It is a condition that should be declared under the item 'has there been any material change that could affect your driving.' If you were involved in an accident and you had not declared that you have glaucoma, then you may not be insured and the DVLA could take action because you have not informed them.

More Information about glaucoma can be obtained from:

The International Glaucoma Association, 108c Warner Road, London SE5 9HQ

Tel 020 7737 3265 or their website www.iga.org/home

Pycnogenol Revisted

Readers may remember that last year IDDT Newsletters [Oct 1999 and Jan 2000] reported details Pycnogenol, a herbal pine bark extract, and the experience of Thomas Petersen, PhD, with Type 1 diabetes for over 47 years. In 1982 Dr Petersen had laser treatment in his right eye for retinopathy and was told that retinopathy that would need treatment was developing in his left eye. After researching for anything that might help to prevent this, he came across Pycnogenol. He began to take it and his retinopathy went into remission and he has not needed any further laser treatment.

IDDT explained that Pycnogenol appears to be a powerful antioxidant which improves circulation by protecting small blood vessels and prevents the oxidation of LDL cholesterol [the bad cholesterol]. Research published in the Journal of Cardiovascular Pharmacology [Oct 1998] showed that Pycnogenol stimulates nitric oxide levels counteracting the blood vessel constricting effects of adrenalin.

Recent Research
In a recent study published in Phytotherapy Research [15;219-233:2001] 30 people with diabetes were treated with 50-mg doses of Pycnogenol 3 times a day for 2 months and a control group of 10 people were treated with a placebo [dummy pill]. The researchers found that in those who took Pycnogenol there was a slowing down of the progression of retinopathy and in some cases the progression actually halted but in the group using the placebo, retinopathy got worse.

Caution!
This is only a small study and therefore it must be treated with caution. However, despite efforts to achieve near normal blood glucose levels, in industrialised countries diabetic retinopathy is still the leading cause of blindness in the working population emphasising a clear need to investigate all possible avenues to prevent people from becoming blind or visually impaired. Therefore IDDT welcomes the findings of this study. It should not be dismissed because Pycnogenol is a

herb but further independent studies are needed using Pycnogenol in greater numbers of people over a greater duration of time.

Warning!
Pycnogenol must not be a seen as a substitute for 'good' control and because of its powerful antioxidant effects should only be used in consultation with your medical adviser, as indeed should all supplements and complementary medicines. It is also essential that the use of Pycnogenol does not replace essential regular eye examinations.

Note – More information is available on the manufacturer's website www.Pycnogenol.com or if you would like copies of the IDDT Newsletters containing the original articles about Pycnogenol, contact IDDT, PO Box 294, Northampton NN1 4XS, tel. 01604 822837 or e-mail enquiries@iddtinternational.org

IDDT News

IDDT Research Funding
Over the years IDDT has made progress and as a result of the generous donations and legacies we receive, we are now in a position to make some relatively small grants for research. The Trustees have given this matter a great deal of thought and made two decisions:

- as a charity whose aims are to help and support people that have diabetes now, our research should be directed towards this aim and not long-term cure, which is adequately funded by other organisations.
- unlike many other organisations, we should take the initiative and commission research in the specific topics that we, people living with diabetes, want researched rather than the topics being those researchers might choose.

This system has the advantage of the research agenda being set by the consumer and not researchers that do not live with diabetes but with experts examining the actual research proposals.

We would like you to tell us the topics where you would like research carried out. The research could be community-based topics involving GPs and primary care issues, hospital based studies, quality of life studies or any aspects of diabetes that you think should be researched.

Please send your suggestions to IDDT, PO Box 294, Northampton NN1 4XS or e-mail your ideas to jenny@iddtinternational.org

Good News for IDDT!
The Lancet has a weekly column describing the websites on various topics. When they covered diabetes, the comment was "fortunately there are many excellent websites for physicians and patients wanting to keep pace with the latest diabetes research and prevention and management strategies". It was good to see that IDDT was one of the seven sites listed along with such organisations as the American Diabetes Association, Diabetes UK and the International Diabetes Federation. For those with access to the internet the sites quoted by the Lancet are:

- The American Diabetes Association at www.diabetes.org
- Diabetes Public Health resource at www.cdc.gov/diabetes
- Diabetes UK at www.diabetes.org.uk
- Insulin Dependent Diabetes Trust at www.iddtinternational.org
- International Diabetes Federation at www.idf.org
- Joslin Diabetes Center at www.joslin.org
- Juvenile Diabetes Research Foundation at www.jdrf.org
- Online Diabetes Resourses at www.mendosa.com/faq.htm

Introducing IDDT
This is our leaflet that is sent to everyone who contacts us. It has been updated and a copy is enclosed with this Newsletter.

Information Leaflets for you from IDDT
As someone of the wrong generation, I have been dragged into this computer/internet era but I now wonder how I managed before! It has increased our ability to communicate, to access information and increased our membership. Indeed, many of IDDT's new members now come from visitors to our website, so we must not knock it! However, we are acutely aware that many people do not have access to the internet and what's more don't even want it! That's fine, but we realise that visitors to our website have access to more information so we are now supplying this information to people without internet access – as free leaflets in good old paper form! They are not posh expensive, glossy leaflets but simple A4 bound copies in easily readable print.

The leaflets cover the following topics:

- Hypoglycaemia
- Diabetes and Eyes
- Weight and Diet
- Neuropathy
- Information for Family Carers
- Information for Parents
- Stress
- Depression

If you would like any or all of these leaflets, then contact IDDT, PO Box 294, Northampton NN1 4XS or tel 01604 622837. A couple of stamps would be welcome!

Sorry – Christmas card time again!
You are always very generous and support IDDT by buying our Christmas cards. We are enclosing a sample of this year's IDDT card and an order form, so could I ask you to support us again this year. If everyone bought just one pack of cards, it would be a great help. The proceeds from this annual fundraiser help with the running costs of IDDT – for example, this Newsletter! Please help us to help you.

Report of the Annual Meeting held in Birmingham May19/20 2001

The meeting was enjoyable and lively. The speakers gave us food for thought and we all learnt a lot from each other. A full report of the meeting and the Annual Report and Accounts for 2000 will be sent to members with the Autumn Newsletter.

IDDT- US

There has been a temporary difficulty in running IDDT-US but hopefully this is now sorted out and Robin Harrison has now got the much needed help and support to continue our operation in the US. Any offers of help from our US members are always welcome.

IDDT in New Zealand

IDDT does not have a formal group in New Zealand but we do have members living there. Therefore we know that there are people in New Zealand suffering the adverse effects of 'human' insulin who need beef and pork insulins in order to control their diabetes effectively. **Jule Connor** is an IDDT member, using beef insulin that she obtains through her pharmacy who import it for her. Jule is very happy to advise other people about the procedure for obtaining beef and pork insulins in New Zealand. Jule can be contacted in New Zealand by telephone on 0321 31087

Insulin Availability in New Zealand is as follows:

Human insulins are the automatic first line treatment.

Pork insulins are not routinely available but on the issue of a

prescription from a diabetes specialist [not a GP], pork insulin will be obtained specially and paid for by the Government Health Department.

Beef insulins are not available in New Zealand and have to be imported. The Government gives no grant towards the costs of beef insulin or the importation costs unless the person is receiving Benefits or is on a low income.

News About Blood Glucose Meters

ALERT - Lifescan PocketScan Blood Glucose Meters

Hopefully by now anyone with this particular blood glucose meter will have been informed of that it should be returned to LifeScan because of faulty software.

The Medical Devices Agency [MDA] issued an ALERT in March 2001 because

a random 'Y' shaped non-numerical character can appear in the test results display and may lead to inappropriate treatment. Apparently this problem only occurs in the meters that measure blood glucose in mmols/l so this Alert applies in the UK.

Recommended Immediate Action

- All users of PocketScan meters should contact the LifeScan customer careline immediately to arrange for a replacement meter. Even if the 'Y' character has not been displayed, users must register for a replacement meter. The telephone number is freephone 0800 121 200
- Do not make diabetes treatment decisions on the basis of a result that includes a 'Y' shaped character.
- If there is any concern about treatment, the user must contact their healthcare provider.

Test strip packs now have a yellow notice sticker on them to alert users to the new information leaflet inside. LifeScan had a communication campaign in order to alert users but they were unable to contact the majority of users because only a very small percentage of users registered their meters with the manufacturer. Perhaps there is a lesson here for all of us – we should always fill in the registration forms for any medical devices so that we are in a position to be informed in case of problems with the device.

The ALERT went to a large mailing list of healthcare providers. IDDT received it from one of our members and immediately put it on our website. We have suggested to the MDA that in future they also mail patient organisations so more people are reached more quickly. We pointed out that it could be months before some people see their healthcare provider and weeks before they collect new blood testing strips.

Note
In December 2000 Johnson and Johnson, who market LifeScan meters, agreed to pay $60 million in fines and a civil settlement over a glucose meter that resulted in incorrect readings. This ended a 3year government investigation into the way J&J's diabetes unit addressed software problems with meters before 1997. Test strips made before March 1998 had also sometimes given false readings.

In April 2001, Inverness Medical Technology, the diabetes equipment monitoring manufacturer, announced a 36% rise in annual revenues to £120.7 million attributing the jump in sales to the take-off of its electrochemical glucose strips that allow blood sugars to be tested without the drawing of blood. True to form, by May 24h, J& J acquired Inverness Medical Technology's diabetes management products business for $1.3 billion.

Launch Of New Meter

DiagnoSys Medical have launched a blood glucose monitor called the Prestige Smart System which has been validated by the Medical Devices Agency. The company say that this meter is particularly suitable for older people because it has a large display of the test result making it more suitable for people with visual difficulties. Major chemist chains, including Superdrug, Numark and Moss Pharmacy, are selling the meter at £7.50 instead of its usual price of £29 until the end of August.

As always this is for information and does not imply IDDT approval for this particular product.

Avoidable Flash Home Glucose Measurement - digital readings upside down

A letter in Diabetes Care [Ref 1] describes an elderly couple where the husband with diabetes had recently had his regime altered. One morning the wife rang the hospital in a panic to say that her husband's blood glucose levels were very high and she had sent him out into the garden to 'work them off'. This was in America where measurements are in mg/dl and the reading was 591 [about 30mmols/l by UK measurements]. A couple of days later, she rang again and this time his blood sugars were 561mg/l, again around 30mmols/l in the UK and again she'd sent him in the garden to work them off! Further investigations into this situation revealed that the couple were looking at the meter upside down and of course some of the digital figures read differently in this situation – so 591 was actually 165 and 561 was actually 195!!!!

This could easily happen with the smaller numbers used in the UK measurements – 5.6 upside down would read 9.5 and 8.1 could be 1.8 etc.

The authors of the letter are recommending that healthcare professionals should be aware of this possibility and meter manufacturers should clearly label their meters to show which is the right way up and IDDT is warning people with diabetes and their carers of this possible problem. It is not a silly warning. Manufacturers should recognise that meters are to be used by people who may well be in the confused state hypoglycaemia. Additionally, they may be visually impaired, they may be elderly and just find things a bit more difficult or it may be the middle of the night when we are all a bit confused!

Ref 1 Diab Care, Vol 24: No 4 April 2001

Did You Know?

- Although the condition of sugar in the urine has been known for 3.500 years, Matthew Dobson was the first doctor to discover a link between sugar and diabetes in Liverpool in 1774.
- The biggest shareholder in Hoechst was Kuwait Petroleum Corporation and they insisted on the merger between Hoechst and Rhone-Poulenc in 1999 to form Aventis who manufacture insulin and many other drugs.

From Our Own correspondents

IDDT Newsletter on audio tape
Dear Jenny,

It is so helpful for those who are visually impaired to actually hear the written word as opposed to having to struggle to read it. Hearing it is also helpful for those with English as a second language. I must congratulate you on the alternating use of both male and female

voices throughout which I found to be an attention holding plus factor.

It is refreshing that the IDDT Newsletter has articles that are so interesting. Keep up the good work.

A.B.
North East

Blood testing recommendations
Dear Jenny,

I cannot agree with the nurse from Cornwall who criticises the blood testing technique described by Ron Raab – using the back of the finger just under the nail. [Spring Newsletter 2001]

In my experience, Mr. Raab's technique is far superior and is one that I have been using for several years. While understanding the concern about not using finger pricking devices to obtain blood, it is worth remembering that when home blood testing first became available, this was the only method of obtaining blood and we all did it quite safely! Perhaps this is a case of practical experience against theory?

Mr S.B.
S East

Class action based on flawed logic
Dear Jenny,

In the Spring 2001Newsletter you ask "Why did the early 1990's legal class action fail?"

If I remember correctly the few studies that were carried out were classed as 'not conclusive' and therefore this was interpreted by the experts in all the relevant bodies as meaning that there was nothing wrong with 'human' insulin. Needless to say this interpretation was flawed logic. Research that is inconclusive means just that – that studies have not been able to demonstrate an answer to the question under investigation of whether 'human' insulin causes adverse reactions or not. I believe that this is why the class action failed.

However, there was another reason that this thinking was flawed. Neither the thinking nor the research took into account that the change to 'human' insulin also meant a change from U20, U40 and U80 strength insulins at the same time for most people.

My husband took part in one of the early studies and he did not show any improvement from going on to U100 'human' insulin. When he took this insulin, it worked for about 3 days and then it stopped. His blood sugars went up and up and no amount of extra insulin made a difference. He went back to U40 animal insulin and it worked perfectly but days later came a sudden, almost impossible to manage hypo, usually at night. It was as if the 'human' insulin was stored in his body and then days later was released. This has happened every time he has tried 'human' insulin and he has been importing U40 animal insulins ever since. Beef worked the best but this is no longer available and so he now uses pork U40. I am sure that if I had not been with him, my husband would have been another of the 'dead in bed' victims.

There always has been a proportion of people whose diabetes is difficult to manage and it may be that these people are like my husband and would do better on U40 insulin but this choice is being denied them.

Mrs M.E
South

Where do I start?
Dear Jenny,

I thought you might be interested in my experiences, but where do I start?

I was diagnosed in 1971 with no problems until 1999. I was on animal

insulin, well-controlled and I felt fine.

After changing to 'human' insulin for a period of about 3 months I started having frequent hypos day and night without warnings but this seemed to settle down. Then in March 2000 they started again and with severe fitting in the night and at my diabetic clinic visit in August I explained the problems to my doctor. But the response was that my HbA1c was too high at 7.5 and it should be 7.00 and advised that I should see the diabetes nurse. She changed my insulin to Humalog [lispro] and Humulin 1.

My hypos continue to this day, are more frequent and without any warnings. I feel extremely tired, nauseous, get confused in conversation or when carrying out simple tasks. At night I cannot sleep because my feet feel so hot, I have tingling in my hands, involuntary jerking in them and they are painful on waking.

I did not have any of this trouble before using 'human' insulin!!!!

Last Autumn reading a copy of Balance, I noticed your letter about 'human' insulin. I rang Diabetes UK and they couldn't tell me anything about IDDT but my Diabetes Nurse gave me a copy of your Newsletter. What a relief that I am not alone with my experiences!

I also learned about Hypostop –no one had told me about this despite my hypos!

Keep up the excellent work of co-ordinating, educating and lobbying.

S.J.
Staffs

Updates

- Inhaled insulin

March 21,2001 - Reuters reported that insulin is expected to be the first of the new category of inhaled drugs on the market. Pfizer, Lilly and Novo Nordisk are all carrying out clinical trials. Pfizer with European partner, Aventis, have announced plans to make application to the FDA for approval in the US by the end of this year. Dr Robert Sherwin, President of the American Diabetes Association is quoted: ***"It looks like a very promising treatment. I like it especially for older people and young children."*** This differs from early statements that inhaled insulin may not be successful in young children because of their inability to inhale adequately.

A spokesman for Aradigm, the company working with Novo Nordisk on inhaled insulin says "It will replace some of the uses of injected insulin. Our primary goal is to increase the insulin market; many diabetics that should be taking insulin before a meal are not taking it. Type 2 diabetes will be our primary market. The market is bigger and the need is greater."

This highlights the difference between drug companies and patients - the goal for people with diabetes is to have the best and most appropriate treatment whatever that might be, not to increase the insulin market!

Later news
April 3rd 2001 - Eli Lilly announced that they have signed an agreement with drug delivery specialist Alkermes Inc to develop inhaled insulins that will be both short-acting and long-acting. Again this conflicts with earlier statements that inhaled insulin will be short-acting only and long-acting insulin will still have to be injected.

May 20th 2001 – the results of the Pfizer/Aventis 2 year trials using Exubera their inhaled insulin in 140 people showed that Exubera controlled blood glucose levels over the two year period noting that

hypoglycaemia was the most common adverse effect with both inhaled and injected insulin. Patients' lung function was found not to be adversely affected but Aventis said that one of the 1000 patients treated so far had developed pulmonary fibrosis – a potentially fatal condition where the lungs develop scar tissue.

However, the trials have shown that only 10-15% of the inhaled insulin is absorbed into the bloodstream but no one seems to know what happens to the remaining 85-90% of the insulin inhaled!

- GlucoWatch

The GlucoWatch has been launched in the UK –the device that we have all been waiting for! It is a sensor that continuously measures blood glucose levels and sounds an alarm when they reach dangerously low levels. It extracts fluid through the skin and glucose levels are measured using this fluid every 20 minutes for 12 hours.

But before you get too excited, the press launch did not make clear that this development is yet far from a safe replacement for conventional finger pricking blood glucose testing. On March 22nd the FDA in the US announced approval of the GlucoWatch. However this approval is, rightly, strictly limited. It will be only be available on prescription to people 18 and over and because of the potential for error the FDA advises that the GlucoWatch should be used in conjunction with conventional finger prick tests. However, the FDA have not yet given approval to the manufacturing facililites and so it is not yet on sale in the US!

Trials have shown that up to 25% of the time the results different from traditional finger prick blood tests by 30%. They also showed that sometimes there were erroneous readings, the GlucoWatch was less effective at very low glucose levels [the ones we really want!] than very high ones and would not measure at all if the arm was too sweaty. It also caused mild skin irritations in at least half the people that used it.

When I contacted the company on the advertised phone line, they could not confirm that the GlucoWatch had been approved by the Medical Devices Agency [MDA] in the UK or that the MDA had issued similar advice to that of the FDA. [We have written to the MDA and are awaiting a response.] Indeed, I could have purchased a GlucoWatch on the telephone without a doctor's prescription.

While this device is a very welcome step forward for people with diabetes, especially to people who have lost their hypo warnings symptoms, it is important that an overzealous approach to the advantages does not obscure the necessary warnings and precautions associated with it.

Driving Update

Good news for drivers of C1 Vehicles - The government's public consultation about the decision to ban people with insulin treated diabetes from driving class C1 vehicles [small lorries and vans between 3,5 and 7.5 tonnes] ended on February 9th. From April 5th 2001 drivers who are treated with insulin will be assessed individually about their fitness to drive. A satisfactory annual medical check up and evidence of good diabetic control will be the main qualifying conditions. The previous requirement to be employed to drive these vehicles and to have held a licence since before January 1997 has been removed.

A separate research project is looking at the risk of hypoglycaemia and loss of warnings and driving.

Information for car drivers with retinopathy
As many of you will know, if you have diabetic retinopathy in both eyes and/or have had laser treatment to both eyes you are required to undergo a visual field test to ensure that you meet the required field standard for driving. Until recently this information has been supplied

by your own ophthalmologist but as a result of delays in obtaining this information from some hospitals, the DVLA is now requesting that people attend one of their named registered optometrists [ophthalmic optician] in their locality for a visual field test. The DVLA send the details of the local registered optometrist to you for an appointment to be made and the optometrist sends the results of the test back to the DVLA.

However, if you have recently had an appropriate visual field test by your consultant and the field charts are readily available from the hospital records **and you make this clear on your licence application**, then the DVLA will approach the hospital for a copy of the field charts.

Word of warning! The above applied to one of our members but when he attended the local registered optometrist, his field check was not carried out by the optometrist himself but by a 'young lady' who was NOT the DVLA registered optometrist and who did not explain the field test procedure very well. Our member wisely asked for a further field test with the DVLA registered optometrist and attended for a second appointment the following day. It is worth remembering that some high street optometrists use non-qualified personnel to carry out a range of tests, including visual field tests. However, if your licence depends on the results of a field test, you need to ensure that the test is carried out by the named, DVLA registered optometrist. IDDT has raised concerns about this matter with the DVLA Medical Unit and our comments have been noted.

Needle Phobia

There are many phobias that affect people and there is a small number of adults and children who have needle phobia – a real fear of needles. It is a great deal more than just 'not liking injections' and of course becomes a very important problem if someone with needle phobia develops insulin requiring diabetes.

It is important that needle phobia is recognised and that assumptions are not made that the child, teenager or adult is just being 'non-compliant' and 'not doing what they should'. It may affect treatment and/or diabetic control by adults and children "forgetting" injections, omitting injections and blood tests or refusing to go on to a multi-dose regime because it means even more injections.

Research carried out in Denmark (ref1) using questionnaires to ask 158 children and adolescents with diabetes about injection pain and needle phobia showed that while most children and adolescents experience only slight pain when injecting, for some pain and needle phobia are major problems. 8.3% of those between 6 and 19 years classed themselves as having pronounced needle phobia. It also showed that there was a relationship between needle phobia, injection pain and diabetic control as measured by HbA1c levels. Those with injection pain had 'poorer' HbA1cs and there was also a clear relationship between needle phobia and injection pain, blood testing pain, the patients' attitude towards diabetes and their mood at the time.

Note: We still know very little about the effects of self-inflicted pain on children, teenagers and adults. It is an area worthy of further research.

Needle-free injections

Needle-free injections devices have been available in the US for some time such as the J-tip Injector [see below] but it is reported that a UK company Medical House, based in Sheffield, is developing a needle-free injection system in the UK. The company has teamed up with US based Bioject to develop Vitjet 3 for administering anaesthetic to dental patients and for injections of insulin.

Vitjet works by forcing the liquid through a small hole in the skin, creating a very fine, high pressure stream that penetrates the skin and goes into the tissue. It is expected that Vitajet will be launched in the UK this summer but it will not be available on the NHS.

For Information:
The J-Tip Injector - IDDT is not endorsing the J-Tip device but we are advising of its availability.

It is possible to have a needle-free injection that delivers the insulin under pressure from a gas cartridge. The J-Tip Needle Free Syringe is 10cms long and weighs only 9 grams. Only the base tip of the device touches the skin. The gas is released by pressing a trigger and this drives the plunger that pushes a piston and the insulin from the sterile syringe through the skin. According to the manufacturers, the insulin is forced through a very tiny hole at high speed in a fraction of a second. The gas escapes from the syringe via a safety hole and never comes into contact with the skin or the insulin.

The manufacturers also advise that the J-Tip Injector dispenses the medication uniformly in a spray pattern in the subcutaneous tissue [skin] and the rate of absorption is faster due to the increased surface are of the fluid. Injection with a needle in the normal way leaves a pool of insulin under the skin and therefore takes longer to disperse and be absorbed. This faster absorption with the J-Tip than with a syringe has implications for diabetic control when used for injecting insulin because the insulin may well work faster.

Warnings:

- The product data sheet warns that this device should be sold under the direction or order from a physician.
- That you should consult your doctor about suitable injection sites and that injection sites should be where there is as much fatty tissue as possible.
- That there have been reports of local reactions such as skin irritation, hardening of the skin, bruising and bleeding.

IDDT Comments:
We repeat - IDDT is not endorsing the J-Tip device but we are advising of its availability. If you have needle phobia and are considering purchasing this device then you must first consult your doctor. We do not believe that this is an alternative to using normal syringes or pens but it may have a place for people with needle phobia.

Similar devices were used some years ago and the major problems were that damage to the skin at injection sites and this was especially a problem for children with young tender skin.

The costs of the J-Tip are:

- In the UK £93.00
- To Europe £98.00
- To all other destinations £89.00

The details of the J-Tip Needle Free syringe can be obtained from:

M. Devices Group, Marlborough House, Riding Street, Southport, PR8 1ERW
Telephone (+44) 01704 544 944
Or by visiting the website at www.merseyworld.com/bennetts/mdg/jtip1.htm

Ref 1 Experiences of pain from injections and needle phobia in young patients with IDDM. Practical Diabetes July 1997, Vol 14: No 4

The Royal Marines Band

On Saturday July 28th, 2001 The Royal Marines Band are supporting IDDT by giving a concert. If you live in the Isle of Wight or happen to be on holiday there, I hope that you will support the fundraising event for IDDT. If you would like details and to reserve tickets, please contact Barbara Holmes on 01983 855753. Tickets are £8.50 and £7.00 for concessions. We are very grateful to The Royal Marines Band for giving their services and to Barbara and her family for organising the event.

Snippets

- Sir Steven Redgrave, the well-known Olympic rower, has become a 'European Ambassador' for LifeScan, the Johnson and Johnson pharmaceutical company that produces blood glucose meters. He will be visiting a number of healthcare events in key European capitals talking about the importance of regular testing of blood glucose levels.
- The Lancet has a short weekly column that asks questions of leaders in the field of medicine and research - the responses are often tongue in cheek! A question asked of Robin Jacoby, Professor of Old Age and Psychiatry at Oxford, was ***'Do you believe in capital punishment?'*** His answer: ***'Emphatically not; except perhaps for Hitler, Stalin, Mao, Pol Pot and Alan Milburn.'*** [Vol 357: March 17,2001]
- A conference entitled Partnerships for Successful Self-Management [of chronic conditions] looked at how self-management can make a difference to people's lives. One of the speakers Professor Sir George Alberti, President of the Royal College of Physicians and an expert in diabetes, said ***"As physicians we become expert in particular diseases and conditions but this cannot give us the insight into how disease affects each individual. Patients with long-term conditions can quickly become experts on how the disease affects them personally and interferes with their lifestyle, and, as doctors, we can learn a great deal about how patients fit treatment and management of their illness into real lives."***
- A report from the International Diabetes Institute says that one million Australians have diabetes – this is one in 20 Australians. This exceeds every Western nation except the US. Professor Zimmet of the Institute, says the epidemic is being driven by overeating, lack of exercise, mechanisation and an aging society.
- In Scotland about 2500 health workers injure themselves on the needles of syringes. The Scottish Executive is spending £270,000 on research into equipment such as syringes with retractable needles to prevent care workers infecting themselves with dirty needles. The US has recently introduced legislation requiring hospitals to use safety syringes for the same reasons. This is seen as a growing market for syringes, especially the prevalence of diabetes is increasing rapidly.

Congratulations To Industry!

To the ABPI!
Pharmaceutical companies sponsor clinical trials into new medicines but these trials are not necessarily published, especially ones with negative results ie that do not show a benefit from a new treatment. Clearly these trials need to be considered by reviewers for the final review to give accurate evidence. The Association of British Industries [ABPI] has set up a voluntary scheme whereby pharmaceutical companies can place their sponsored trials on a database to be available to researchers, healthcare professionals, patients and other interested parties. This is a welcome move towards the greater openness that we and others seek.

The site can be accessed on the internet – www.controlled-trials.com

To Novo Nordisk Ltd
Diabetes Specialists in Leicester are to receive £150,000 over the next 3 years from Novo Nordisk to support education work about diabetes to the Asian community. Specialists in Leicester will be putting their knowledge into the national setting with a new website giving information about their research and it will also provide patients with access to educational materials that have been developed especially for the Asian community.

Good News For Finland

People in Finland, as in other countries are facing the discontinuation of their beef insulin made by Novo Nordisk but there is good news for them. CP Pharmaceuticals Ltd, the UK manufacturer of natural animal insulins, have been granted marketing authorisation for Hypurin Bovine Lente" under the European Mutual Recognition Procedure. This means that CP have not had to carry out new research but that the regulatory authority in Finland has accepted their existing dossier of information. This is excellent news for people who need Bovine Lente insulin.

If you would like to join IDDT, or know of someone who would, please fill in the form (block letters) and return it to:

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PO Box 294
Northampton
NN1 4XS

Name: ——————————————————————————

Address: ——————————————————————————

——————————————————————————

Postcode: ——————————————————————————

Tel No: ——————————————————————————

From Your Editor – Jenny Hirst

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