Registered Charity No 1058284 - Issue No 28

Insulin Dependent Diabetes Trust

April 2001 Newsletter

Why We Continue To Fight!

A recent article in Practical Diabetes [Jan/Feb 2001 Vol 18 No1] confirms our reasons: **"Severe hypoglycaemia with loss of consciousness and possible convulsion is a most distressing and life threatening situation."**

Readers are only too well aware that one of the main adverse reactions in some people using synthetic 'human' insulin always was, and still is, hypoglycaemia and loss of warnings. The original research into Lilly's 'human' insulin was carried out by Professor Harry Keen and his team at Guy's Hospital and published in 1980. It showed that 'human' insulin was effective at lowering blood glucose levels but it also showed that there was a greater risk of hypoglycaemia with 'human' insulin. The participants were not using insulin at all, they were healthy non-diabetic men, and so this increased hypoglycaemia could not be due to a change from animal insulin. IDDT's Winter 2001 Newsletter quoted Lilly research as early as 1981 that showed that 'human' insulin was absorbed faster and therefore was more likely to produce hypoglycaemia than animal insulins. So all these facts were known even **BEFORE** 'human' insulin was licensed and on the market!

We know that many within the medical profession, the nursing profession, the government health departments and diabetes organisations around the world do not believe that there are problems of hypoglycaemia with 'human' insulin. But it is no longer a matter of what they believe, but one of fact. Read on…

As a result of the information in IDDT's Winter Newsletter, one of our members wrote to the Medicines Control Agency [MCA], the

body responsible for the licensing and monitoring of drugs. IDDT has written to the MCA countless times and received nothing other than fairly dismissive responses, especially the latter ones from Lord Hunt! However our member's letter went to a different person at the MCA and look at the response this time!

Differences between human insulin and animal were known about when human insulin was first licensed. The early product information for Humulin [Lilly human insulin], one of the human insulin products licensed in 1982, included the following information for prescribers:

"Transferring from other insulins: A small number of patients transferring from insulins of animal origin may require a dosage reduction, especially if they are tightly controlled and bordering on hypoglycaemia. The dosage reduction may occur immediately after transfer or be a gradual process lasting for several weeks. There is a risk of hypoglycaemia if insulin requirement is decreased, and both the physician and the patient should be aware of this possibility. The risk can be considered minimal if the daily dosage is less than 40IU. Insulin-resistant patients receiving more than 100IU daily should be referred to hospital for transfer."

*See the end of this article for Product Information for Novo and Nordisk 'human' insulins.

Remember that this information was for 'prescribers' – our doctors! The significance is enormous because it points out the following:

In 1982 there was a known risk of hypoglycaemia.

In 1982 physicians were advised that they should inform their patients of the risk of hypoglycaemia.

In 1982 it was known that 'human' insulin would affect people differently - those with tight control were likely to be at greater risk of hypoglycaemia, that some people would be affected immediately and others over a longer period. It was known that some people should be transferred to 'human' insulin in hospital.

The true significance of this information is that in 1982 Eli Lilly DID provide this information to prescribers stating that DOCTORS and PATIENTS should be aware of the risks of hypoglycaemia.

- Were patients and carers given this information? NO THEY WERE NOT.
- Isn't this information just what patients have been saying for years? YES IT IS.

This warning was NOT provided directly to patients in the Patient Information Leaflets until the early 1990s – 9 years later and after many people suffered unnecessarily. There was a failure to communicate this information to the very people who were using 'human' insulin but the real question that needs answering is, where does the responsibility for this failure lie?

With the insulin manufacturers?

1. Why did they wait until the early 1990s before voluntarily putting warnings of the risk of hypoglycaemia in the Patient Information Leaflets [PILS]?
2. When there is increasing evidence from patients that the adverse reactions also occur in people who have never used animal insulin, why do they still insist without evidence that the adverse reactions only occur in people who have changed from animal to 'human' insulin.

With the MCA?

1. Why did the MCA not insist that warnings were included in the PILS in 1982 and certainly in the mid-80s when the numerous adverse reactions were reported?
2. Why did the MCA not issue an alert when the problems started to appear?
3. Why have the MCA never provided this product information to

IDDT in their numerous responses to the letters from IDDT?

4. Why does the MCA continue to insist that they have no concerns for the safety of 'human' insulin when they have always known that there is a greater risk of hypoglycaemia and loss of warnings compared to animal insulin?
5. Has the MCA and Dept of Health never been advised by their diabetes experts that [quote] 'severe hypoglycaemia with loss of consciousness and possible convulsion is a most distressing and life threatening situation' and is unsafe? If not, why not? The Dept of Transport has!

With the medical profession and their diabetes experts?

1. Why were patients not given this information?
2. Why did the medical profession, especially the experts, not immediately recognise the problems their patients were having, as being the same as those described in the Product Information?
3. Why were patients with the adverse effects not only fobbed off but also accused of making up the problems, being neurotic and some even referred to pyschologists?
4. Why did they run the risk of being in breach of their NHS contractual arrangements in this way simply for a new insulin with no proven benefits that was certainly not desperately needed?
5. Why were patients not warned of a possible need for a dosage reduction until the early 1990s?
6. Why did they, and do they, show an apparent lack of concern for any increased risks of hypoglycaemia and loss of warnings that may be as a result of 'human' insulin?

With Diabetes UK [the BDA]?

As Diabetes UK has a very large medical and healthcare membership all of the above questions must also apply to them especially as the professional members are an integral part of their decision making process. But because Diabetes UK/BDA is a patient based organisation set up to look after the best interests of all people with diabetes, there are very specific questions that must be asked of them:

- When the then BDA received overwhelming evidence from their members in the mid 1980s [3000 unsolicited letters] with adverse reactions to 'human' insulin, why didn't they immediately and publicly express concerns on behalf of their members?
- Why did the BDA and their medical advisers, not immediately recognise the problems their patients were having, as being the same as those described in the Product Information?
- Why did the BDA NOT listen to their members with diabetes and allow those with the adverse effects not only to be fobbed off but also to be accused of making up the problems?
- Why did the BDA fail to tell its members through Balance and Diabetic Medicine that the Product Information advises that there is a risk of hypoglycaemia if insulin requirement is decreased and also that a dosage reduction may be required? [The latter was not stated until the early 1990s.]
- Why didn't the BDA make the facts in the Product Information known publicly?

These questions have been directed at the UK situation but let us not forget that these very same questions need to be asked in other countries too.

It is not for IDDT to answer these questions. But one thing is certain, people with diabetes and their families, especially those that suffered as a result of 'human' insulin, deserve an apology. Those that are struggling with 'human' insulin now deserve an open-minded approach and the opportunity to try natural animal insulin. People that have unexplained hypos and/or loss of warning symptoms deserve the option of trying animal insulin. Those that have never even received the information that natural animal insulins are available and are less aggressive than 'human' insulin, deserve this information and choice.

But there remains one final question:
Why did the early 1990s legal class action taken by patients with these adverse reactions fail?

The complaints from patients and their carers were of increased

hypoglycaemia and loss of warnings. The warning about hypoglycaemia was included in the 1982 Product Information. So just why did the legal action fail? We were told that it was for 'lack of scientific evidence' but there must have been scientific evidence for the information to be in the Product Information for prescribers. Indeed, we now know there was! Anyway it was not in the manufacturers' interests to make it up – it was not exactly a selling point for 'human' insulin! I doubt there is a person on this earth that would have changed to 'human' insulin if they had known there was a greater risk of hypoglycaemia.

But in reality, in directing the class action against the manufacturers, was it being directed at the wrong people? Lilly provided information about the adverse reactions to prescribers, so could they be held responsible for the information not reaching patients? If they weren't responsible, then who was?

Finally to act as a reminder to those who may just forget, we started this article with this quote: "Severe hypoglycaemia with loss of consciousness and possible convulsion is a most distressing and life threatening situation." If one person suffers this experience as a result of using 'human' insulin, it is unnecessary and one person too many. If one person has a severe hypo and dies as a result of using 'human' insulin, it is unnecessary and one person too many.

*FOR INFORMATION:

Novo Laboratories Ltd for Human Actrapid and Human Monotard licensed in 1982:
"Precautions: On transfer from porcine monocomponent insulins or other highly purified porcine insulins to human monocomponent insulin, no change in dosage is anticipated other than the routine adjustments made in order to maintain stable diabetic control.

Patients currently stabilised on mixed species or bovine insulins may require a dosage adjustment dependent upon the dosage, purity, species and formulation of the insulin(s) currently administered. Variations in glycaemia control may occur and adjustments in therapy should be made under the guidance of a physician."

Nordisk-UK for Human Insulatard licensed in 1985:

"Diabetics previously treated with beef or mixed beef/pork origin may have to have their dosage adjusted downwards if changed to Human Insulatard."

For Human Mixtard licensed in 1985:

"Patients treated with other commercially available beef or mixed beef/pork origin may require to have their dosage reduced when transferred to Human Mixtard. The dosage reduction may be immediate or occur over a period of a few weeks or months."

Intersting Quotes!

"Preliminary reports and the opinion of patients did not completely eliminate the belief that human insulin may be dangerous, particularly during the transfer from animal insulin. It is true that the efficacy of human insulin was not fully evaluated on a large scale or in long-term randomised controlled trials, nor were its adverse effects."

Safety of Human Insulin in Poor-Sighted Elderly Diabetic Patients. Diabetes Care, Dec, 1999 Jean-Jaques Altman, MD, PhD et al

"Despite an extensive research effort, the question of whether human insulin does affect the awareness of hypoglycaemia remains unproven. In clinical practice there are undoubtedly a small number of people with insulin-treated diabetes in whom the use of human insulin has been very unsatisfactory, being associated with frequent and unpredictable hypoglycaemia and a diminished sense of well-being. Whether this is related to the different pharmokinetics of human insulin or is an idiosyncratic

response in affected individuals is unknown, but there is clearly a need for insulin manufacturers to maintain the availability of animal insulins for such patients."

Hypoglycaemia in Clinical Diabetes – a book edited by Frier and Fisher published by John Wiley & Sons.

"However, there is yet no conclusive evidence that this [loss of hypo warnings] is due to human insulin.'

Balance, Diabetes UK March 2001

Interesting –this means that there is evidence but it's not conclusive. 'Yet' implies that there is an expectation that there will be conclusive evidence.

Diabetes UK Closes The Youth Department

Recently Diabetes UK [the BDA] announced the closure of this department although the holidays and family weekends will continue. Now does not seem the right time for Diabetes UK to close down the Youth Department. Not only is childhood diabetes increasing but we now also have MODY appearing – a form of type 2 diabetes in children and young people.

The treatment of diabetes may have become better but parents still face the same fears, conflicts, insecurities and emotions that have always been there. The treatment of childhood diabetes arguably places even greater responsibilities on both parents and children than in the past. The emphasis on tight control with the increased risk of severe hypos, the need for blood testing and the knowledge needed for interpreting and acting upon the results adds to the responsibilities and anxieties of parents and their children. It is effective help with all these aspects of diabetes that is so very necessary for families living with diabetes.

We need to be constantly looking at ways of helping families to cope with the difficulties of bringing up children with diabetes and ways of making life easier. Families need help, support and understanding and not just at the time of diagnosis. Research, workshops involving parents and paediatricians to explore ways of helping parents and their children and the development of self-management courses are just some of the options to explore that could lead to a better life for families living with diabetes.

The closure of Diabetes UK's Youth Department means that there is no longer a focal point in the UK for looking specifically at life with diabetes for children, young people and their parents.

- Will all the issues affecting families with diabetes be addressed as a priority area?
- What could be more important than helping children and young people with diabetes to grow up happy, well adjusted and healthy?

It is effective help with these aspects of diabetes that is so very necessary for families living with diabetes.

Fact:

The rate of young children developing Type 1 diabetes under the age of 5 has increased considerably. The UK figures show that cases of juvenile or Type 1 diabetes in the under-fives have doubled in the last 10 years.

These statistics are frighteningly high and need addressing urgently.

Unlike Type 2 that can be blamed on the lifestyle changes of increased lack of exercise and obesity, Type 1 diabetes in children cannot. Let us not forget that 'cure' is only one answer and research into cause and prevention surely must be a priority. While we continue to wait for 'the cure', more and more little children will have to put up with living

with diabetes and more and more families will have their lives totally changed by the intrusion of diabetes. While we wait for the 'cure' the years of living with diabetes will take their toll on these little children

Has the emphasis in research changed?
Yes, there is a far greater emphasis on research into Type 2 diabetes. We recognise that Type 2 diabetes can also cause the awful complications of diabetes. We also recognise that there is a huge cost factor to health providers in the increasing number of people diagnosed with Type 2 diabetes. And yes, we recognise that children with diabetes are only a small proportion of the whole diabetic population. But let those who control or have some influence over research funding remember that there are other issues in diabetes as well as the economic ones – our children with diabetes are the most vulnerable group within the diabetic population.

We only need to look at two examples to know that diabetes in children and young people must be treated as a priority.

Little Jemma Walsh - she is just two years old and has diabetes. Her Mum, Jayne, says "Jemma has two injections a day and regular blood tests which she hates but thankfully she's OK. Jemma hasn't had a bad hypo yet, it's something I am dreading. I'm also dreading her going to school when I won't be able to keep an eye on her all the time." Jayne is expressing feelings that are familiar to all parents of little children with diabetes but Jemma is not a statistic she is her little girl and it is both normal and natural that she will worry about her.

Matt Brett - he is now 18 years old and has had diabetes since 1997. Matt has been swimming for 5 years and since he was diagnosed he has won a gold medal and two bronze medals at the British National Championships and last year was third in the Olympic trials for backstroke. Diabetes has not deterred Matt from achieving great things in his swimming but in order to maintain good control during all his training he takes between 5 and 8 injections of Humalog a day and a longer acting insulin before bed. If Matt continues his current level of success, not only will he provide hope and inspiration to many young people with diabetes in the future but he is also demonstrating that it can only be done with a great deal of attention paid to his diabetes. IDDT has offered Matt a little help with his costly training because we felt that he deserved some help along the way!

Children and young people with diabetes never know what real freedom is like and have to live their whole lives with diabetes and its effects. My daughter fits into this category, perhaps she doesn't know what I mean by real freedom because she can't remember life without diabetes. Her diabetes has not stopped her doing anything she wanted to do but she has never known freedom from it! I know that at 30 years old her 26 years of diabetes have already started to take their toll. We need more research into cause and prevention but we also need more research into how best to help families to cope with living with diabetes.

IDDT News

IDDT Annual Meeting - May 19/20th, 2001
Comfort Inn, Hagley Road, Birmingham

Details of our Annual Meeting 2001 have already been sent to you and you will realise that this year we are including an overnight stay to enable members from further afield to be able to join us for what is always a lively and enjoyable meeting. The meeting will have an international flavour with speakers from Australia and the United States as well as nearer home. The meeting will start with coffee at 10.15am on Saturday morning and will finish with lunch on Sunday. We are inviting you to come along either on a daily basis or for the whole weekend – the choice is yours and we hope that you will bring friends or members of your family with you.

During the weekend we will be discussing the insulin situation, the present dietary recommendations and low carbohydrate diets. There

will be plenty of opportunities for your views.

Just to remind you, the charge for the whole weekend including Saturday accommodation and all meals will be £20.00 per person and if you just want to come along for the Saturday only, the charge will be £10.00 per person. We hope that you will be able to join us - your views are important to us. It is our opportunity to meet you and your opportunity to meet us.

Send your application form in now to IDDT, PO Box 294, Northampton NN1 4XS, telephone 01604 622837 or e-mail meeting@iddtinternational.org

Denmark - Welcome To IDDT

We are pleased to announce that there is interest in forming an IDDT group in Denmark. Jesper Graversen is 31 years old and has insulin dependent diabetes. He recognises that it took him time to come to terms with diabetes and contact with other people helps with this. He found IDDT website useful and informative and believes that other people in Denmark would also benefit from this contact. So we have set up a website for Denmark in both English and Danish that can be reached by visiting www.iddtinternational.org and clicking on the Danish flag. IDDT in the UK is happy to offer Jesper all the support and help that we can.

Jesper strongly believes that people with diabetes should obtain their insulin free of charge and he would welcome other people's views on this.

Anyone wanting to contact Jesper can do so by e-mail jesper.graversen@12move.dk

Talking meters

The latest situation is that Joan Allwinkle, a diabetes specialist nurse in Edinburgh is doing a tremendous amount of work to try to ensure that reliable 'talking meters' are available for people who have visual difficulties. She is being supported by Gareth Jenkins, the national sales manager for Lifescan. The present position is that they have been reviewing four voice synthesisers and the selected one is undergoing tests to meet the European criteria for medical devices. Once this has been achieved the synthesiser will be advertised in the RNIB catalogue and service arrangements will be through Lifescan.

IDDT has been in touch with both Joan and Gareth and we can vouch for their commitment to try to help people with visual impairment. We are grateful for all they are doing and look forward to a successful outcome and one that will provide the necessary independence for people who are blind or visually impaired.

IDDT has continued to receive desperate calls from people with visual impairment or their carers. Indeed, we received reports of people having to go into care over Christmas because of a lack of staff to visit them at home. IDDT has therefore been providing information that voice synthesisers that can be used with a One Touch Profile or Basic meter can be obtained from the US at a cost of approximately £120 plus import duty. We strongly recommend that this is only done with the advice and help of your diabetes team.

Voice Synthesisers can be obtained from:

Independent Living Aids Inc., 27 East Mall, Palinview, New York 11803-4404, USA

Telephone 001 516 752 8080

IDDT Newsletter available on tape

We are pleased to announce that from this issue forward IDDT's Newsletter is available on tape for the blind and visually impaired. We

already have a list of people who want to receive the tape version, but if you would like to do so, or know someone that would, then please let us know in any of the following ways:

Tel 01604 622837 Fax 01604 622838 e-mail tape@iddtinternational.org or in writing to: IDDT, PO Box 294, Northampton NN1 4XS

IDDT Newsletter available in different paper versions

Readers will be aware that we already produce the Newsletter in A3 size with large black and white print. We are also now making the Newsletter available for people who use magnifying reading machines and require A4 size paper. You can obtain the Newsletter in black and white, point 14 Aerial print suitable for these machines. Again of you would like this version, or know someone that would, then contact IDDT as above.

Note: we will continue to send the large print version to those already on our mailing list unless we hear otherwise.

Thank you

The Trustees would like to say thank you to all our members for their continued support in renewing their membership subscriptions, making donations throughout the year and for purchasing IDDT Christmas Cards. Not only does this enable IDDT to continue and to grow as an organisation but this support encourages us to continue with our aims and objectives.

In addition to donations from our members, we are also receiving significant legacy income. We are very grateful to all those who have thought of IDDT in their Wills. We regularly receive donations in memory of loved ones and to all those who think of IDDT at what can only be described as a sad time for relatives and friends, we say thank you for helping us to help others.

Two High Profile Lectures But The Message Is The Same -The medical profession has to change!

President of the GMC critical of government and the medical profession

January, 2001

The Lancet reports that in a recent lecture Donald Irvine, the president of the General Medical Council, criticised both the government and the medical profession for failing to address the quality of healthcare. He said that the NHS was in ‘crisis’ and spoke of inherent ‘cultural flaws in the medical profession’. In particular he pointed to ‘excessive paternalism’ and ‘secrecy and complacency about poor practice’. As for the government he urged them to increase the number of doctors, to create a ‘no blame culture’ and remove the ‘layers of heavy external regulation’.

This is quite a turn round for the GMC and one that will be supported by patients. We will have to see if the President’s words bear fruit.

The Lord Chief Justice says his piece too

January, 2001

In his inaugural provost’s lecture at University College London, Lord Woolf said that in the past English courts were ‘excessively deferential’ to doctors in their reluctance to find them guilty of negligence. Judges are now less willing to allow the medical profession to determine what amounted to negligent practice because it has become clear to the courts that ‘the hospitals and medical professions cannot be relied upon to resolve complaints justly’. Lord Woolf explained that in the past a doctor would not be found negligent if his/her practice was accepted as proper by a responsible body of medical opinion. But this is no longer enough and now the medical opinion has to withstand logical analysis. He said that the moral of his lecture was that it was

'unwise to place any profession, or other body providing services, to the public on a pedestal where their actions cannot be subject to close scrutiny.' Commenting on the recent high profile medical scandals, he said that those involved were not motivated by personal gain but had lost sight of the limits of their powers and authority. They acted as though they were able to take any action they thought desirable irrespective of the views of others.

These are the views of a leader of the medical profession and a top English judge and they are ones with which most of us ordinary mortals would probably agree although we might wonder if this public debate would be taking place at all if there had not been the series of medical scandals over the last couple of years.

Let us not forget that there are good caring doctors out there but there are still quite a few who have not realised that there have been changes in our society that are bound to affect the medical profession as well as everyone else. We have a society that not only has fundamental rights but now it knows it has and these rights apply to healthcare as well as every other aspect of life. Gone are the days when the doctor was respected simply because he/she was a doctor - the automatic respect and power their qualifications gave them has gone. We need informed choice and evidence to support their advice in exactly the same way as we do for other members of society.

So how do these lectures apply to the 'human' insulin situation?

Many of us know from our own experience that as patients we were not, and still are not given our fundamental rights of informed choice of insulin and even worse, some people are actually denied the option to have animal insulin – quite unjustified on the grounds of the scientific evidence. There never was, and still isn't any evidence to support the case that 'human' insulin has any clinical advantages for patients over animal insulin. The prescribing of 'human' insulin may well be the accepted wisdom of 'a responsible body of medical opinion' but that opinion did not, and does not, stand up to 'logical analysis or close scrutiny', to quote Lord Woolf!

When the class action was attempted in the early 1990s, I am sure that none of the people who suffered adverse reactions to 'human' insulin wanted to go down the legal route. They had already raised their complaints in every possible way with the Department of Health, the then British Diabetic Association and the drug companies. They were ignored and their problems denied by experts in diabetes and this is the power to which Lord Woolf refers and the excessive paternalism and secrecy to which Donald Irvine refers.

If the 1990 class action had taken place in today's climate, how different would the situation be?

Now courts recognise that patients face real difficulties in resolving their complaints justly and that courts should not rely solely opinion of a group of responsible doctors.

- Would it be recognised that perhaps the experts in diabetes did not have an entirely unbiased opinion because many of them were also the same group of people who carried out research into the 'human' insulin trials for the drug companies?
- Perhaps nowadays the courts would recognise that the very fact that the first published paper by Professor Harry Keen showed that there was a greater risk of hypoglycaemia with 'human' insulin actually supported the case of the patients with these very same adverse reactions. Perhaps the courts would question why this evidence was ignored and if this was negligent?

Past experiences may have been due to the excessive paternalism of the medical profession, may be that they didn't like patients rejecting their prescribing or maybe it was a wish to hang on to the all powerful doctor image of knowing better than their patients. To some people this may be just history, to people with diabetes it is not just history to be dismissed or swept under the carpet -the value of history is to learn from past errors.

Non-Invasive Detection Of Hypoglycaemia Using A Novel And Patient Friendly Alarm System

This is the title of an article in the BMJ in December 2000 by Professor Gareth Williams and his team at Liverpool University Hospital including three dogs. It starts off seriously by pointing out that hypoglycaemia is one of complications of diabetes most feared by patients because it:

- is often distressing and carry risks of serious neurolgical and cardiovascular damage
- is especially hazardous in cases of long-standing Type 1 diabetes with loss of warnings
- is potentially dangerous if hypos occur at night and has been implicated in the dead in bed syndrome.

However, the article goes on describe 'a novel alarm system for detecting hypoglycaemia before the patient notices any symptoms' based on three cases voluntarily reported by three patients – their dogs.

Case 1 – a lady who when hypo, her dog uncharacteristically jumps up, runs out of the room and hides under a chair in the hallway and only emerged again when the lady had treated her hypo.

Case 2 – a lady who has about two hypos a week during the afternoon or at night. Her dog nudges her awake and will not go back to sleep until the lady has treated the hypo. The dog has even prevented the lady leaving the house until she has taken carbohydrate to correct a hypo.

Case 3 – a lady who has about two hypos a week, has reduced warnings and does not wake up with night hypos. Her dog becomes very distressed when she is hypo. During the day he paces up and down and puts his head on her lap and during the night he barks and scratches the bedroom door. He only settles after she has treated her hypo.

There were of course some common factors in all three cases – all three ladies sweated when they were hypo, obviously easily sensed by their dogs. No doubt their dogs also sensed their changed behaviour when hypo. Also common to all three cases was that the dogs only detected the hypos when the blood sugars were 1.5, 2 and 1.6mmols/l respectively. It is noticeable that the team from Liverpool expressed no concern that blood glucose levels were going down this low and two of the ladies are even described as having generally good hypo warnings! If this is so, why are their blood sugars going down this low before they notice?

While the article does point to the other ways in which dogs are used to help people with medical conditions, clearly it is meant to be amusing. As someone who lived with loss of warnings in my daughter while she was on 'human' insulin, I am afraid that my normally good sense of humour does not apply to hypoglycaemia unawareness! I think others may feel the same!

Note: It was interesting to see that the media must have picked up on this because there was a flurry of articles about people whose dogs detected their hypos first.

1984 May Be Well Gone But...

The New Health and Social Care Bill is described as 'Orwellian'

In this new Bill, Alan Milburn, the Health Secretary, wants to outlaw awkward independent reports on standards and treatment in the NHS and rely on official studies to monitor all aspects of the NHS. Any group or individual trying to produce independent reports will be subject to fines of up to £5,000. This means that patient and consumer groups will not be able to do spot checks on hospitals or clinics or measure the effects of treatment. So the government will have powers to control all reports on every aspect of the NHS including quality of care.

Unbelievably, he also wants to disclose patients' medical records to third parties for research purposes, even if patients and their doctors object. Is this legal????

Consumer and Patient Organisations are united in their opposition to these proposals declaring them to be Orwellian and undemocratic. How else can they be described? Add to this Bill the following:

- In January this year, the Government abolished the Patients' Charter which has given patients rights since 1948. This is being replaced 'Your Guide to the NHS' which replaces 'rights' with 'expectations'. Expectations remove all patient powers. The Guide also emphasises patients' responsibilities of not missing appointments, doing exercise and practising safe sex! This is frightening and paves the way for all sorts of possibilities - will the time come when we can only have expectations of the NHS if we carry out our responsibilities of exercising and practising safe sex????
- Community Health Councils, the statuary independent patient watchdogs, are being abolished and replaced with Patient Advocates – much weaker bodies that can't be as independent because they are appointed by the local hospital and report to the hospital chief executive!
- The College of Health, an advice line that helps patients avoid long waiting lists has lost its public funding.

All these changes and proposals are the most insidious and dangerous changes since the NHS was introduced in 1948 and cannot under any circumstances be of benefit to patients. They will serve to add to the distrust patients and consumers already have. Indeed, we are already suspicious because it seems remarkable that these changes are happening when the NHS and the medical profession have been criticised like never before! No wonder this government failed in its promise to have an effective Freedom of Information Act!

The 'Human' Vs Animal Insulin Debate Will Never Go Away As Long As People Continue To Suffer

In the UK we have been debating and campaigning about the adverse effects of 'human' insulin for some people for many years and there has been considerable publicity. People in Canada and the US are now actually being denied the beef insulin they need and being threatened with unavailability of pork insulin and they are using the media to raise awareness of the effects of losing the drug they need – all in the name of commercial decision-making! IDDT reports on the recent media coverage.

CBC Marketplace, Canada TV,

Health problems linked to synthetic insulin

Reporter – Erica Johnson,

13 February 2001

There has previously been little publicity about the adverse effects of synthetic 'human' insulin in Canada, unlike the UK. Their situation now is reminiscent of that in the UK a few years ago except that Canadians have already lost their beef insulin and pork is increasingly more difficult to find. This report on Canadian national television has brought an influx of people with the classic adverse reactions to 'human' insulin to IDDT contacts in Canada, to the IDDT-International website and IDDT membership forms have been flowing in to IDDT in the UK. The one thing nearly all these people have in common is that they have been told by their doctors that they were the only ones with the problem! Perhaps of some comfort is that at least now they know they are not the only ones and there is a whole group of people experiencing similar problems in countries around the world.

Key points in the report:

- A British Columbia woman, Colleen Fuller, is set to launch a lawsuit against the makers of 'human' insulin saying that it put her in a coma. She says she will also name Health Canada [the equivalent of our Dept of Health] claiming that they have a duty to provide alternative treatments.
- Health Canada has confirmed that since 1998, it has received 121 reports of problems related to 'human' insulin use including comas, seizures, convulsions and hypoglycaemia. They also stated that they do not have the authority to force a manufacturer to continue marketing something they have chosen to withdraw for their own corporate reasons. In the United States the FDA says it has received thousands of similar reports.
- Warnings on the packaging of Eli Lilly's Humulin state that a few patients found their early warning symptoms of a hypo were less pronounced than with animal insulin. But Lilly's, Dr Grossman told Marketplace that 'There is no evidence from clinical studies that there is a correlation, or a cause and effect relationship between human insulin and these symptoms that you're referring to.'
- Colleen Fuller is not convinced that the Canadian Diabetes Association [CDA] has done enough. Four years ago CDA asked its members if they were having trouble switching from animal to 'human' insulin. 43% said they were and she makes the point that CDA had a duty to follow this up. Marketplace also reported that the BDA report looking at some of the 3,000 letters of complaints about 'human' insulin was not published because they considered it to be "too alarmist".

The report quotes the following people:

- Professor Arthur Teuscher, one of the first physicians in the world to prescribe 'human' insulin. He changed his mind after seeing how one of his patients reacted and told Marketplace: " He had an abrupt, sudden, hypoglycaemia. He was rushed to the University Department and after 3 days he was dead."
- Dr John Hunt, an endocrinologist who has treated dozens of patients struggling on 'human' insulin says that he does not see how pharmaceutical companies can deny that some people are having problems. "To say that somebody doesn't exist, when they're having major problems…they know the solution, and the solution is being removed from them. I think this is immoral. If Health Canada were at all sensitive to their people, they would say if people really need animal insulin, let's make it easy for them rather than making it as difficult as we possibly can."
- The Canadian Diabetes Association spokesman, Martin MacInally, told Marketplace that they 'definitely asked Lilly and Novo Nordisk to reconsider their decision to discontinue the popular animal insulins but the companies said the decision was final.'

Needless to say this has angered Colleen Fuller who knows her crusade will not be easy but she sees it as the fight for her life and those of others who have adverse reactions to 'human' insulin

Both Lilly and the CDA responded to Marketplace with open letters and CDA even copied theirs to the Prime Minister! A bit over the top perhaps?

This is a case of shooting the messenger! In their letter the day after Marketplace, both Lilly and CDA are highly critical of the programme for upsetting people and causing them to question their treatment.

Interestingly Lilly make the bald statement that 'human' insulin is better than animal insulin but naturally they fail to justify this statement with reasons or evidence from research. Both Lilly and CDA assert that there are very few people having problems with 'human' insulin because there are so few people using animal insulin –flawed logic!

1. Many people in Canada are unaware that pork insulin is still available and they have remained on 'human' insulin because they believed there was no alternative!
2. Canadians contacting IDDT, are mainly people who are actually using 'human' insulin and having the problems we all know so well.

3. For many people the adverse effects of ‘human’ insulin do not occur at changeover from animal – they occur after duration of use of ‘human’ insulin and they occur in people who have never used animal insulin. IDDT’s 1994 questionnaire clearly showed that on average the problems started to occur after 13 months using ‘human’ insulin.

But CDA express their view that “there is no convincing scientific evidence to support a clinically significant difference in the frequency of or in the symptomatic response to hypoglycaemia between animal and human insulin.”

In other words CDA, like other organisations, does not believe its own members - the very people with diabetes who have experienced the adverse effects. Perhaps even worse, they are not listening to them either. But why not? It is a mystery!

National associations are supposed to have the welfare of all people with diabetes at the core of their activities. People that need animal insulin may be a minority group, but they are not just statistics. Each and every one of the people who struggle with ‘human’ insulin is a real live person who deserves the best possible health with the best possible quality of life. Furthermore, each and every person with diabetes including those who are apparently happy on ‘human’ insulin, deserves to know that long-term, large scale trials comparing ‘human’ and animal insulin have been never carried out to provide evidence on which to prescribe ‘human’ insulin as a better treatment than animal insulin.

Latest News – People in Canada are now gathering together and have already met with solicitors to discuss class action.

Fox 13 Investigate - TV, USA

The Insulin Crisis
Report by Glenn Selig,

February 2001

Glenn Selig covered the problems with ‘human’ insulin in a couple of excellent TV programmes starting in 1999. He has continued to pursue this issue and perhaps because, like us, the more he looks, the more there is to discover or perhaps he sees the actions of the major drug companies as being immoral and uncaring. If this is so, many of us would agree with him!

The latest investigation deals with ‘dead in bed’ syndrome – the unexplained deaths of people with diabetes who seem in perfect health, but are found dead in or near their beds.

Glenn Selig asks if some people are being harmed by the insulin they take and he looks at the death of Susan Mescher who never let diabetes keep her from enjoying life. She travelled a lot – a fringe benefit of being a top travel agent with American Express. Her sister says you’d never know Susan had diabetes because she managed it so well. She used beef/pork animal insulin twice a day. So it came as a complete shock to the family when four months ago Susan died. After 37 years the 49year old switched to Humulin, synthetic ‘human’ insulin by Eli Lilly and Company and three weeks after Susan took her first injection, she died.

Key points from FOX 13 Investigates:

- They examined the Food and Drug Administration [FDA] records and over a 12 month period, the agency received complaints from doctors and family members about 92 people who died while taking Humulin. In most cases there is no explanation given but three of them were listed as ‘Sudden Death and Unexplained’. In addition more than 600 people claim to have been hospitalised.

- Dr John Hunt an endocrinologist Vancouver, says all insulins are not the same and some might be better than others for some people. Dr Hunt says that with diabetes, remedies and dosages vary from person to person so you might have three different diabetics on three totally different regimes and insulins.

The FDA acknowledges that 'human' insulin may not be right for everyone – for the first time.

The FDA would not be interviewed for this report, but in a statement, for the first time they acknowledge that the 'human' insulin may not be right for everyone but they say there's no crisis because there are options "if patients cannot tolerate human insulin."

Here is part of the FDA Statement:

"There are patients who report that they have more hypoglycemia with human insulin than with animal insulin. For these individuals, pork insulin continues to be available in the U.S. Patients who believe that they cannot use human insulin can use pork insulin. It is notable that since the approval of the first human insulin product in the early 1980's, most newly diagnosed Type I diabetics are treated from the start with human insulin.

For some patients being treated with animal insulin, the switch from animal insulin to human insulin may be complex. The drugs are not directly interchangeable for a variety of reasons. Intrinsic characteristics of the drug products that affect their speed of onset and duration of action may lead to more or less pronounced effects on glucose levels depending on the specific product used. In addition, most people taking animal insulins develop antibodies to the foreign insulins that affect speed of onset and duration of action. When such individuals switch to human insulins, the levels of these antibodies fall such that the speed of onset and duration of action of the human insulins are not similarly affected…

None of the points mentioned above is intended to suggest differences in the safety of animal insulins versus human insulins. All insulins can cause hypoglycemia, an adverse effect that may be associated with severe consequences including seizure, coma, heart attack, stroke, and in rare instances, death. It is important to note that most patients can switch to human insulin without difficulty."

Lilly's response from their Medical Adviser, Dr John H Holcombe M.D, made in writing and here are some of the points:

"There is no question about the safety of Lilly's human insulin, Humulin. Your hypothesis that animal based insulins are safer than human insulin is completely without merit. In fact the American Diabetes Association states that "Human insulin has become the insulin of first choice for newly diagnosed patients with diabetes and is recommended by the American Diabetes Association for patients beginning insulin therapy."

Millions of patients and physicians around the world can attest to the immeasurable benefits of this life-saving drug. Based on 2000 Roper Starch Syndicated Research, nearly 3.725 million people in the United States use insulin to treat diabetes. In contrast, less than 1% of these patients use animal insulin, the majority of which is represented by a currently marketed product, Iletin II, purified pork insulin.

For over 75 years, Lilly has been a leader in diabetes care and research. Today, we continue the quest to make life easier for all people with diabetes. And as a member of the Tampa community, you are undoubtedly concerned with the health and safety of your friends and neighbours with this disease. To repeatedly cause undue concern and alarm is not only harmful but also irresponsible."

Worth a note that this 'leader in diabetes care' does not care enough to keep patients, doctors and pharmacists informed because there is no mention of the availability of pork insulin on the company's website! When FOX 13 phoned around, only about one in ten pharmacies had it in stock.

Perhaps we can pick up on some very careful guarded words:

- Lilly quotes the American Diabetes Association [ADA] “Human insulin has become the insulin of first choice for newly diagnosed patients with diabetes and is recommended by the American Diabetes Association for patients beginning insulin therapy.” This recommendation only refers to the newly diagnosed – not to people who may have had diabetes a long time, not to people who may have complications, not to people who are known to be prone to hypos. This list is endless and one wonders what ADA’s recommendations are for these people?
- Lilly says that only 1% of people are using animal insulin in the US – said as a percentage this doesn’t sound many but in reality it is actually around 37,000 real people!
- The FDA say - “It is important to note that most patients can switch to human insulin without difficulty.” What is supposed to happen to the people who can’t switch and the people who can’t switch from beef to pork insulin? What happens to the people who believe their pharmacy when they are told that Lilly has discontinued pork?

Useful Gadgets

Holidays Again!

At this time of year we are hoping for a warm or even hot summer with holidays and days out. It is important to keep your insulin cool whether you are at home or abroad – even a day on the beach in this country can be too hot to just leave your insulin in your bag or pocket. So we are just reminding you of FROI Wallets designed to keep your insulin cool and safe for 48 hours, even in temperatures of 100 degrees Fahrenheit. The main advantages are that there are no bulky ice packs, you don’t have to worry about finding a freezer to get supplies of ice and the wallet is light to carry.

How does the FRIO wallet work?
It is activated by immersing it in cold water for 5-15 minutes. The panels of the wallet contain crystals and these expand into gel with the immersion in water. The wallet remains at a cool temperature for several days, according to the prevailing conditions. The system relies on the evaporation process for cooling. Drying the wallet with a towel makes it dry to the touch.

The FRIO wallet comes in four sizes:

- Individual – for carrying one pen and some cartridges where continued availability is required. Cost £12.00
- Small –for two 10ml vials of insulin. Cost £12.50
- Large –for one pen and two sets of cartridges or 4 10ml vials or 5 disposable pens. Cost £14.50
- Extra large – this has 3 or 4 times the capacity of the large wallet and is most suitable for a long stay or expedition type transportation. Cost £18.99

All the costs include postage and packing within the UK. The device has been approved by the British Medical Devices Evaluation Unit. For further information or to order a wallet contact the manufacturers at:

FRIO UK, Freepost SWC 0667, Haverfordwest, SA62 5ZZ.

Interestingly! FRIO has been asked to design a cooling device for Formula One racing drivers when they have to bear very high temperatures in their helmets and fire proof overalls during races. FRIO is trying to design a kit that will fit inside the driver’s overalls and helmet. They have also been asked to design a cooling jacket for insulin pumps. Research into this in the US has so far failed but FRIO’s jacket is being tested on a mountaineering expedition in the Andes.

Reminder Watch - MeDose

This is a useful device developed originally in Sweden for children with diabetes. The watch has six built in alarms that either sound or vibrate to act as reminders for adults and children to take their medication or to do a blood test. For parents, it gives some reassurance that their child or teenager will be reminded to do a blood test or take their insulin when they are away from them while at the same time giving the kids a greater sense of independence from their parents.

The MeDose adult watch comes in silver/black and children's ones come in blue or red with a velcro band and uses a standard replaceable watch battery. It is available from the US priced 79.95 US dollars with a charge of 15 dollars for shipping to the UK. There is a 30day money back guarantee and a one year warranty. IDDT has contacted the company and they regularly supply to the UK. Orders can be made by post, e-mail or on the company's website, the details are as follows:

e-pill, LLC, 70 Walnut Street,
Wellesley, MA 02481,
USA
Phone 001 781 239-8255 Fax 001 781 235-3252
e-mail address is sales@epill.com Website is www.epill.com

Books - Follow Up

Readers will remember that one member requested information about books that were a little bit more than the simple ones we read when diagnosed and ones that would provide information to stimulate questions on clinic visits. We have decided to simply publish a list of books that people have found useful and let you decide!

- "ABC of Diabetes" by Professor Peter J Watkins,

This book covers the many aspects of diabetes from diagnosis, treatment, the complications to the organisation of diabetic care.

It is published by BMJ Publishing Group ISBN 0 7279 1189 9

- "Understanding Diabetes" by Dr Rudy W Bilious,

This is a useful little book in the Family Doctor Series and is a practical guide to helping people with diabetes to take more responsibility for their own health and well-being. It offers lots of advice about diet, home blood monitoring, treatment and routines.

It is published by Family Doctor Publications in association with the BMA price £2.49 and can be obtained from many pharmacies.

- *"Diabetes at Your Finger Tips" by Peter Sonksen, Charles Fox and Sue Judd*

This is a question and answer book and includes many of the questions many of us need answering. It is an easy reference book to be dipped into when a question arises.

It is published by Class Publishing ISBN 1-872362-02-8

"The Diabetic Woman", Lois Jovanovic-Peterson, June Biermann, Barbara Toohey

Every section of this book contains practical information that women can use on a daily basis to cope with having diabetes. It covers many of the questions that are unique to women with diabetes and that they are reluctant to ask their doctors. There is also a section for family member and friends to provide greater understanding of life with diabetes. It is written with sensitivity and humour.

It is published by Penguin Putnam Inc ISBN 0-87477-829-8

Inhaled Insulin And Islet Transplants - Let's Not Get Too Carried Away!

IDDT retains a press cutting service to collect everything in the UK national and local press about diabetes. It is sometimes surprising what the press regards as important or a 'significant breakthrough'. In the last 3 months there has been little to choose between coverage of islet transplantation and inhaled insulin – huge numbers of cuttings for both.

Inhaled insulin

The media coverage was amazing especially when you realise that it came from a study that merely provided evidence of 'proof of concept'. In other words, the study has only shown that inhaled insulin did actually reach the blood stream safely and rapidly but it is too early to conclude that it is as good as conventional injections. The results of the study [The Lancet, Vol 357; Feb 5 2001] show that inhaled insulin does not abolish the need for injections altogether as the headlines suggest because long-acting insulins will still have to be given by injection.

In his commentary in The Lancet, Professor Edwin Gale recognises that injections for some people are symbols of 'their bondage to the invisible parasite' of diabetes. However, he also points out that inhaled insulin is only a small step forward perhaps only worthy of two cheers and not three in our society but it is worth no cheers at all in a world where children in poor countries die because they cannot get any insulin at all. This problem could be solved for about 1% of the development costs of each new luxury insulin!

It is a pity that the media do not cover this aspect of inhaled insulin – that drug companies go on developing fancy insulins of dubious value while children and adults die for lack of affordable insulin. But this is not where profits come from – far better to spend money selling their products to health professionals in the Western World than saving lives in poor countries – a scandal that rarely sees the light of day.

Islet Transplants

This is progress and not to be knocked but nevertheless we have to see it in perspective. Amid claims that this could revolutionise diabetes within 10 years and that there is the potential to help 130 million people with diabetes worldwide, Dr John Shapiro who carried out the successful research, told the BBC:

'The treatment does involve risks and will not be suitable for all diabetics. But those with severe diabetes or who often lapse into comas could benefit. We have to balance the risks of the treatment procedure and anti-rejection drugs against the risks these patients face everyday.'

This rather contradicts the Appeal for funds leaflet from Diabetes UK that claims that 'If successful, it could mean the end of insulin dependent diabetes within a decade.' We just need to have our feet on the ground a little bit! Who is going to fund this 'end of diabetes in a decade', if it comes?

On January 26th Diabetes UK announced that, with the University of Leicester, they are to set up trials for islet transplants at an initial cost of £300,000. The trials will take place at 7 centres across the UK and they hope to perform 10 islet transplants this year. This will involve taking islet cells from a donor and injecting them into the liver of the person with diabetes.

Note: The significance of stem cell research, recently given the go ahead by the government, is that theoretically islet cells could be developed from stem cells and if taken from the person having the transplant, they would not be rejected so that anti-rejection drugs [immuno-suppressants] would not be necessary.

Participants

Before we all go rushing off to volunteer, IDDT looked at the details of one of the trials already recruiting participants in the US [ref 1]. Participants must have had Type 1 diabetes for at least 5 years and must show one of the following:

- hypoglycaemic unawareness, or more than one hypoglycaemic reaction in the preceding 20 months that required outside help.
- metabolic instability,
- evidence of early but progressive secondary diabetic complications but which have not progressed to end-stage renal failure;
- failure of intensive insulin management.

There are over 20 categories of what you must NOT have to be a participant including cardiac problems, obesity, no history of 'non-compliance' etc.

Unanswered questions
Apart from the obvious research to ensure that this procedure is safe and effective, there are other questions that will need answers. For instance what happens to hypoglycaemia in islet transplant patients? Does islet transplantation eliminate hypoglycaemia?

Successful transplantation of insulin producing islets should eliminate high blood sugar levels. But researchers anticipate that the transplanted cells will only produce insulin and not the glucagon which, with adrenaline, is the body's natural mechanism for preventing hypos by raising blood sugars. This study may find out if regulated insulin production alone can prevent hypoglycaemia. What happens if it doesn't? Recruiting is taking place in the US for research to examine this very important question. [ref 2] So there is still a long way to go…..

Note: Last year as a result of a request for funding from Leicester University, IDDT donated £2000 to the islet research in Leicester, this was of course before the Shapiro research made the headlines. We are glad that Diabetes UK has now decided to take on the funding of this project.

Ref 1 National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), Bethesda, USA

Ref 2 Philip E. Cryer, M.D. Washington University School of Medicine

What Irritates Me...

- Is when my consultant at the clinic says to me, as a parting shot "Try to keep better blood glucose levels". He never tells me how to make them better and I do actually try!
- What irritates me is fat dieticians who lecture me on healthy eating and exercise!

From Our Own Correspondents

Blood testing recommendations – correction!
Dear Sir/Madam,

I just wanted to respond to an article by Mr Ron Raab [IDDT Winter Newsletter 2001].

As a Diabetes Specialist Nurse I obviously respect everyone's wish to carry out blood testing at the most comfortable site for them, but the article seemed to suggest that the finger tip is the most commonly recommended site

For many years now, myself and colleagues have taught both health professionals and diabetic persons that the upper sides of the finger are the recommended sites because of the very reasons Mr Raab mentions ie fewer nerve endings in these areas and also less direct use for people with manually dextrous hobbies or jobs.

Also I would like to point out, that several finger pricking devices now have settings to control the depth of the penetration. Suggesting manual pricking, especially by a syringe, I find rather worrying as enthusiastic 'jabbing' could cause injury leading to infection.

Ms RC
Diabetes Specialist Nurse

Cornwall

Jenny's comment: I would like to thank Ms RC for this letter and for informing IDDT and our readers that using the finger-tip is no longer the recommended place for blood testing. I was certainly unaware of this change in the recommendations, as I am sure are many of our readers.

They need IDDT in Southern Ireland!
Dear Jenny,

I recently visited Southern Ireland and thought I had taken enough animal insulin with me but I stayed longer than originally intended and ran out of my insulin. There is no animal insulin there and I had to re-take 'human' insulin at £22.00 a bottle. There is certainly a need for IDDT in Southern Ireland. What happens to people who need animal insulin?

Mrs H.D. Midlands

Jenny's comment – the answer to the last question is that they either get it by special arrangement or they have no option but to use 'human' insulin. But there is a lesson here for everyone using animal insulins – they are disappearing from more and more countries all the time so it is essential that you carry plenty of animal insulin with you, even if you end up throwing some away at the end of your holiday. Better that then being caught out!

Even more waste?
Dear Jenny,

I read with interest that many of the insulins are now going to be in 3ml cartridges for pens. I do not understand the logic of this change from 1.5ml cartridges especially when the expiry date for in use insulin is 28 days. Surely this will mean many of us will be discarding more insulin because we cannot use up the whole cartridge within 28 days? This seems a waste of insulin and a cost to the NHS for supplying insulin that we throw away. The only people to gain from this are the manufacturers of insulin – once more!

In addition to this does anyone else remember the first lovely sleek Novopen? The reason it was called a pen was that it resembled a fountain pen in size and appearance so that it was more socially acceptable than syringes. Pens have become bigger over the years and with 3ml cartridges they have to increase in size even more. They no longer look like pens but a medical device, which of course is what they are.

Mr D S. W Midlands

Warning To Pharmacists

As a result of a number of reported incidents of the wrong insulin being supplied to patients by pharmacists, the January 2001 edition of the Pharmaceutical Journal has reminded pharmacists of the need to be vigilant in ensuring that the correct insulin is dispensed. The common mistakes were porcine for 'human' and vice versa, Humalog Mix 25 instead of Humalog, Human Mixtard 30 instead of 50 and the Penfill cartridges instead of pre-filled pens. Pharmacists are advised to segregate insulins with similar packaging in the refrigerator, to make careful checks when giving to the patient and possibly to check with the patient that they recognise the insulin as the one they are expecting to receive.

We would reiterate our advice that you should always check that you have received the correct insulin BEFORE leaving the pharmacy.

Preparing For Surgery

The Drugs and Therapeutic Bulletin [DTB], a medical journal published by the Consumers Association for doctors, has focussed on issues around surgery for people who have diabetes, who are taking HRT, the contraceptive pill or various heart or blood pressure drugs. They have looked at this because drugs normally taken could be affected by the surgery itself or the drugs needed as a result of the surgery. DTB claims that the lives of some patients needing operations are being put at risk because doctors do not take proper account of the medication they are taking before they arrive at the hospital. The Bulletin called for a full inquiry into this issue.

DTB concludes that the GP, the hospital doctors and pharmacists need to avoid or plan for potential problems before the person is admitted to hospital. IDDT would also add that if this were the case, then people requiring animal insulins when in hospital, would not be faced with its lack of availability and the battles to obtain it before an operation.

IDDT recommends that if you are to have a planned admission to hospital, then you should discuss your medications with the doctors involved before your admission.

HRT and the pill - some women are told to stop taking these medications about 4 weeks before an operation because anyone having major surgery or leg surgery is at risk of developing a blood clot. This risk is increased in women who take HRT or the pill. DTB concluded that stopping medication is not necessarily the best way because it increases the risks of pregnancy and also the return of menopausal symptoms. DTB suggest that other preventative measures can be taken including wearing special stockings and taking the blood thinning drug heparin.

Did you know?
Every year over a million people have surgery, ranging from very minor to major surgery such as heart surgery but the things that happen in hospital are very similar. Many us have no idea what to expect, how to prepare for an operation and what is expected of us when we get into hospital.

"Under the Knife, a guide to having surgery" is a little booklet that answers these questions and also provides useful information to help ensure that your recovery is smooth. It also tells you how to make hospitalisation less upsetting for children.

The booklet is easy to read and very helpful. It was produced to accompany a Channel 4 programme shown in June/July 2000.

"Under the Knife" can be obtained by sending postal order or cheque, payable to Channel 4 Television, for £1.20 [incl p&p] to:

Under the Knife, PO Box 4000, Manchester M60 3LL

Research Request

IDDT has been approached by a university to help provide patients that have experienced problems with 'human' insulin. The research does not involve any change of your insulin. It entails collecting information about you and your experiences with different insulins. The aim of the study is to try to identify the types of patients that are more likely to be not suited to 'human' insulin. If you would be interested in helping with this analytical research, please write to Dr Kiln at the usual IDDT address.

Low Carbohydrate Diet

Once again there has been a large response to the discussions on

low carbohydrate diet as a result of the report IDDT sent out with the Winter 2001 Newsletter and we hope that this will be further developed at our May Meeting. It seems that people with diabetes are slowly starting to question the logic of a high carbohydrate diet that pushes up the blood glucose levels and requires a greater dose of insulin to bring them down again. As IDDT pointed out we require evidence from research to demonstrate that the dietary advice that we are using is correct and is evidence based rather than just assumed to be the best. There is nothing wrong with a re-think or questioning present dietary recommendations especially when there have been so many changes in diabetes over the last 10 years – insulins are different, regimes are different and we have targets of tight control. Dietary recommendations have not been reviewed since all these changes came on the scene.

At the American Diabetes Association Conference in June 2000 a small study was presented of low carb diet among 69 Type 2 diabetics over a 3 month period. [Ref 1]

29% of the diabetics followed a diet with carbohydrate intake limited to 40grams/day, 39% followed a diet that limited carbohydrate intake to 80grams/day, and 32% could not follow the diet. After 3 months the results showed the patients who were able to follow either the 40g or 80g carbohydrate diet had lower HbA1c levels, lower fasting insulin levels, lower bodyweight, and lower total daily insulin dosages in diabetics using insulin. The diabetics following the 40g carb diets had lower triglyceride levels as well.

Interestingly, a paper in Practical Diabetes [Ref 2] again referring to Type 2, says ‘One of the problems for today’s diabetic patients is that the portion sizes are too large at meals’.

Ref 1Berez PB, The Use of Insulin Levels and Low Carbohydrate Diets in the

Management of Type 2 Diabetes. ADA Scientific Session, Abstract #1849-PPO)

Ref 2 Glucose peaks- the hidden danger in Type 2 diabetes. Prac Diab Jan/Feb 2001 Vol 18 No 1 Supplement

Note: People wanting more information about the Low Carb approach can obtain Dr Richard Bernstein’s book called ‘Diabetic Solutions’. It is available from Amazon Books on the internet or most good bookshops will obtain it for you.

Pig-Kissing Contest Must Change Name

London Metro, January 2001, reports that a children’s pig-kissing contest in Colorado is being forced to find a new name because another organisation claims it owns the Kiss a Pig concept. YouthZone, a children’s organisation, has run the annual fundraiser in Roaring Fork Valley for ten years. The group was so pleased at raising $112,000 (£75,000), it entered the event in a fundraisers’ competition and won. The prize included an article in a national magazine.

YouthZone then received a letter from the American Diabetes Association[ADA] saying that it had trademarked the Kiss a Pig name. Jerry Franz of ADA said: “We’re not trying to be heavy handed. We’re just trying to protect something that is important to us.” He says that pigs hold special meaning for diabetics because they provided the first insulin.

Note: Insulin from pigs was not the first insulin to be used. the first insulin was from cattle. What a shame that ADA did not appear to try so hard to protect what actually was the first insulin, beef, from discontinuation! Let us hope that they take as firm action to protect pork insulin from discontinuation.

Pharmaceutical Industry News

Industry's proposal to avoid postcode prescribing
The Association of British Pharmaceutical Industries [ABPI] has set out its proposal to enable the National Institute for Clinical Excellence [NICE] to end the lottery of healthcare in the UK, to achieve faster access to modern treatments and to encourage innovation. Their three main points are:

- Government must ensure that money earmarked to finance NICE recommendations reaches its target.
- Government must put pressure on health authorities who use NICE as an excuse for perpetuating the current lottery of care.
- The Dept of Health should provide 'a window of opportunity' for new medicines launched in the UK.

Well, they would say all that wouldn't they! But the ABPI do add a polite threat by maintaining that unless the system changes there is a real risk that pharmaceutical companies are unlikely to select the UK as an early market for new medicines. They maintain that this will undermine the UK as a successful base for future research and development of new and better medicines as a result of which patients will have slower rather than faster access to innovative treatments. No doubt this is meant to encourage consumers to support industry's stance. Perhaps they need to remember that consumers may have a different agenda - they want to see an end to postcode care but also want to ensure that treatments and medicines are safe and that information about the drug trials and any reported adverse reactions are openly available to the public.

FDA proposal new rule for gene therapy research
We read much about gene therapy as the way forward to cure many illnesses, and diabetes is one that is frequently quoted. The Food and drugs Administration [FDA] in the United States have a proposed a new rule that, if adopted, will significantly increase the amount of information that they will make available about gene therapy research. Public concern and scrutiny started after the death of a teenager in 1999 as a result of a side effect in a gene therapy trial that, according to experts, should have been anticipated from the animal trials and side effects in other people.

The proposal will also apply to xenotransplantation where cells or organs from animals are transplanted into people, another area of research in diabetes. If adopted the rule will require the FDA to release full descriptions of all clinical studies, copies of the informed consent forms that participants must sign, the monitoring procedures for the participants, a constantly updated record of safety problems in humans and a record of any disciplinary actions by the FDA for each study.

This proposal is a deviation from the FDA's normal policy of keeping information about clinical trials secret. It seems that this rule is being proposed as a direct result of public concern over the new technology – a shame that the public concern over clinical trials of new drugs and treatments cannot be addressed with similar degrees of openness! The US consumer group, Public Citizen, also share this view and will be pushing for similar disclosures in all human trials for all drugs. But as we might expect, the Biotechnology Industry Organisation attacked the rule as unnecessary for patients, harmful to the fledgling field of genetic medicine and perhaps illegal.

European bodies discuss the future of drug regulation
On January 11th the European Federation of Pharmaceutical Industries and Associations (EFPIA) held "The 2001 Review of Pharmaceutical Regulations"

Legislation Workshop. Present were representatives of the policy-makers (high-level representatives of the European Commission, Parliament, Economic and Social Committee, the EMEA and national agencies from 14 Member States) and users of the marketing authorisation procedures for medicines in Europe (regulatory professionals and senior executives of the pharmaceutical industry). They discussed their differing perspectives on the issue of Europe-wide regulation. The Director General of the EFPIA made it clear that

the current system remains unduly complex, is duplicative of EU and national activities, and is structurally unprepared to meet the challenges of an expanding EU. Amongst the reforms suggested to improve the centralised procedure were the establishment of Therapeutic Working Groups and the setting up of appeal mechanisms to ensure that fair judgements are made. To enhance the decentralised procedure the EFPIA advocates a rapid issuance of national licenses and a 10-year data protection in all countries.

Attacks on the pharmaceutical industry continue

The withdrawals of 11 drugs in four years appears for safety reasons appears to be unprecedented in the US. Only eight prescription drugs were pulled for safety reasons in the previous 26 years.

“We are seeing the breakdown of a system that was far from perfect to begin with,” said Daniel A. Hussar, professor of pharmacy at the Philadelphia College of Pharmacy. Critics fault drug companies and the Food and Drug Administration for the approvals of drugs they say are questionable, and they chastise Congress for under-funding the FDA and pressuring the agency to play ball with drug companies.

The monitoring system for drug safety is so weak and under-funded that Americans do not know for sure which drugs are causing the most serious problems, why they are causing problems, or what measures would help reduce the future toll. The questions about drug safety arise after a successful 10 year push by Congress and the pharmaceutical industry to get the FDA to approve drugs more quickly.

For Your Amusement!

A panel of distinguished people from business, politics, science and the media put their heads together and came up with the top 300 most powerful people in year 2000. We’ve picked out a few for you, the ones related to health matters and thrown in one or two more to put the list into perspective – if this is possible!

1. Tony Blair – Prime Minister
7. Bill Clinton – President of the US, at the time
24. Sir Richard Sykes – Chairman of Glaxo Wellcome, pharmaceutical company
41. Liam Donaldson – UK Chief Medical Officer
49. Rt Hon Alan Milburn – UK Secretary of State for Health
50. William Hague – leader of the Conservative Party
74. The Queen
124. Robert B Shapiro – Chairman of Monsanto, pharmaceuticals and biotech
132. Prof Sir John Pattison – Director of Research and Development at the DoH
204. Dr Jane E Henney – Commissioner, Food and Drugs Agency, US Government

Interesting that The Chairman of Glaxo Wellcome, a pharmaceutical company is seen as more powerful than our Secretary of State for Health and by 52 points! Also of interest is Dr Jane Henney, a member of the FDA in the Clinton era as she was a major player in the discussions about the lack of availability of beef insulin in the US.

Where To Find Us

UNITED KINGDOM
Contact Jenny Hirst or Kirsty Bevan

IDDT
PO Box 294,
Northampton NN1 4XS

Tel 01604 622837 Fax 01604 622838

e-mail enquiries@iddtinternational.org

AUSTRALIA
Contact Larrane Ingram

PO Box 3041,
North Rockhampton Shopping Fair
QLD 4701

e-mail jack@rocknet.net.au
Telephone contact Michael Ginges 0061 2 9419 8234
e-mail michaelginges@start.com.au

CANADA
Contact Carol Baker

Box 30165
Saanich Cewntre Postal Outlet
Victoria, B.C. V8X 5E1

001 250 4778564
e-mail iddt_cda@yahoo.com

DENMARK
Contact Jesper Graversen

e-mail jesper.graversen@12move.dk
FINLAND
Contact Leena Paasu

Tel 00353 13 285188
e-mail leena.paasu@kolumbus.fi

GERMANY
Contact Sissi Kuhn-Prinz

INSULINER-VERLAG

Naizissenweg 17
G-57548 Kirchen

Tel 0049 274 930040 Fax 0049 2741 930041
e-mail Insuliner@t-line.de

SWITZERLAND
Contact Prof Arthur Teuscher, MD

Insulin Forum Switzerland
Bremgartenstrasse 119
CH-3012 Bern

Tel 0041 31 302 4233 Fax 0041 31 302 8210
e-mail info@insulin.ch
web site http://www.insulin.ch

UNITED STATES
Contact Robin Harrison

2514 Wilbon Street
Durham
NC 27704-3045

Tel Toll free 1-888-568-7237 Fax 001 919 220 4237
e-mail info@insulinchoice.org
Websites for all the countries with IDDT groups or groups affliated to IDDT can be found by visiting IDDT-International's website at www.iddtinternational.org

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

IDDT
PO Box 294
Northampton
NN1 4XS

Name: ——————————————————————————

Address: ——————————————————————————

——————————————————————————

Postcode: ——————————————————————————

Tel No: ——————————————————————————

From Your Editor – Jenny Hirst

IDDT welcomes the submission of letters and editorial articles for consideration of publication in future issues of the IDDT Newsletter. The editor and trustees do not necessarily endorse any opinions or content expressed by contributors and reserve the right to refuse, alter or edit any submission before publication. No part of this publication may be reproduced in any form without the prior written permission of the editor.

Insulin Dependent Diabetes Trust
PO Box 294
Northampton
NN1 4XS

tel: 01604 622837
fax: 01604 622838
e-mail: support@iddtinternational.org
website: www.iddtinternational.org