Insulin Dependent Diabetes Trust

January 2000 Newsletter

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The Year 2000

Whenever I put the Newsletter together I always have to remember that you will actually be reading it some weeks later. I am writing this in early November to cope with the time the printers are not at work over the Millenium celebrations. I promise you that this is the last time in this Newsletter that I shall use the word 'Millenium'. It is not that I am a killjoy, but I wonder if we have got it all a bit out of perspective. I wonder if, after all the hype, people will feel a bit deflated when they realise on January 4th 2000 that life is exactly the same as it was before. The bills roll in, work carries on, the weather is awful and, if you live with diabetes, it will still be there.

Having sounded a real misery, I do wish all of you a happy New Year. Perhaps these words are often lightly spoken, but it is the one time in the year when we give a simple, kind message to those around us. We hope that the year to come is a happy one for our friends and families. For people who are having a difficult time and the wider populations around the world who don't have all the advantages that we have, it is sometimes a difficult message and may be not an appropriate one but underlying the words, are our good wishes for them. So I don't see this year as any different from any other and my message is a genuine one – I hope that the New Year is a happy one for all of you.

Don't have any special expectations of IDDT simply because it is the year 2000, but do expect us to carry on as usual! My practical self says that we will all become immune to the various celebrations and charity events after the first three months and time, effort and money to raise awareness of an issue like diabetes could well be wasted. We have waited years for the big 'breakthrough' in diabetes research and it is as far away now as it was when my daughter was

diagnosed nearly 25 years ago. For those of you that now think that the woman writing this article really is an old misery, you may be right. I am certainly getting old but I prefer to think that I am just realistic rather than a misery!

Nevertheless, a New Year is a time for reflection and a time to look to the future.

When I reflect on the activities of IDDT, it is still partly a miracle that we have survived, certainly financially, yet alone become an international patients' organisation for people with diabetes and their families. But when I look ahead, there is much to be done. In relation to 'human' insulin, it is not going to be very productive to keep arguing about the research that has been done – there are no new studies and the validity of some of those that were carried out has to be questioned. It seems that the essence of what we need to achieve is to change the attitudes of the medical and nursing communities.

- They have to be convinced of the need to listen to their patients,
- to not dismiss their patients' reports of adverse reactions to 'human' insulin and treat these experiences as a valid form of evidence,
- to recognise that anecdotal evidence is the basis of adverse drug reaction reporting and drug surveillance.

If we could achieve all these things, then the drug companies would have real difficulties in continuing to withdraw animal insulins without a superior alternative. This superior alternative has not been found. But let us not delude ourselves, this is not going to be easily achieved with 'human' insulin – too many people will have to climb down from their very entrenched positions and admit that perhaps they got it wrong!

Looking to the future, we have to continue to try to convince these same people of the need to maintain supplies of animal insulins for people with diabetes, wherever they may live in the world. I don't know if this is even possible but when the health and wellbeing of people are at stake, we have no alternative but to continue to try.

During the next year our emphasis will be on the actual problems that people have when using 'human' insulin – increased severity of hypoglycaemia, lack of awareness of it. If there is a greater understanding amongst those who do not have diabetes but treat people who do, about the effects of hypoglycaemia on our daily lives, it is hard to believe that they would not take every opportunity to reduce the risks of unnecessary hypos. If natural animal insulin is one option to try and we know works for some people then, as caring people with their patients' best interests at heart, they surely must, in all conscience, go down this route. **So during the year 2000, IDDT will be emphasising the importance of the effects of hypoglycaemia – a condition caused by the treatment of diabetes, not by diabetes itself.**

The other range of symptoms such as extreme tiredness, confusion, mood and personality changes will also receive more attention. They are largely ignored, probably because these symptoms are not easily accepted or measured by scientists who are used to standard methods of research. There are now methods of research that can look at patients' experiences in a measurable way. IDDT will be pursuing this approach in the year ahead.

As more people approach IDDT, it is clear that the problems do not simply occur for people who were originally on animal insulin and then transferred to 'human'. They are also happening to people who have only ever used synthetic 'human' insulin and so we are fighting for natural animal insulins to be available for their future needs too.

If I am allowed one wish for the future treatment of diabetes, it is to go back to the days when our doctors could say to us 'You can't die in a hypo if you become unconscious because the insulin will run out and you will come round' and to go back to the days when seizures and comas in children were not as common. I don't blame all of this on the introduction of 'human' insulin but believe that these shorter acting, more aggressive synthetic insulins must play their part, as must intensive therapy.

LATE NOTE: Having already written this, I have to add that during the week of checking the draft, I have received four articles from various newspapers, which cover different stories of people being found unconscious, having motor accidents or behaving in an out of character fashion and involving the police. We have followed them up and all were hypoglycaemic and all were taking 'human' insulin. These articles are appearing with increasing and frightening regularity. I am angry that no one is listening to us and our concerns and I have to say at the beginning of this new year, that we will leave no stone unturned to see that this issue continues to be highlighted. If we are wrong and 'human' insulin is not the cause of the problem, or the combination of 'human' and intensive therapy, is not the cause of the problem, then it is time that research is carried out into this subgroup of people who have the range of symptoms and hypos without warnings. There has to be a cause, why is no one looking for it?

If I am allowed a second wish it is that someone should independently fund a large, long-term sensible study that takes us right back to the drawing board in the treatment of diabetes and asks some fundamental questions by comparing treatments with the various regimes and different insulins. It seems to me that treatment has grown like Topsey rather than as a result of hard evidence to demonstrate the way forward. Is it possible to have a treatment regime to reduce the complications of diabetes and have a realistic level of control that avoids the damaging effects of severe hypoglycaemia?

A Few Quotes To Take With Us Into The Years Ahead - Only Some With Tongue In Cheek

Regulatory Bodies

- "The Committee on Safety of Medicines concluded that some patients did experience problems with 'human' insulins, particularly when initially transferred from animal insulins and were better suited to continuing their treatment with animal insulins. However, the CSM found no evidence of a safety problem specific to human insulin. Indeed, most patients responded well on it." Baroness Hayman, Parliamentary Under Secretary of Health, August 19 1999.

- "A few patients who have experienced hypoglycaemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycaemia were less pronounced or different." ***U.S. Food and Drug Administration label warning on biosynthetic human insulin in bold-faced type.***

In relation to the DCCT and hypoglycaemia

- "It's an enormous problem [hypoglycaemia] and it's becoming more common across the world as people push harder to control their diabetes." ***Patrick Boyle, University of New Mexico Health Science Centre.***
- "The whole spectrum of blood sugars is shifting downwards, but the dark side is that it increases the rate of hypoglycaemia." ***David Nathan, Massachusetts General Hospital.***
- "We saw a lot of seizures, comas and spouses trying to wake up their partners in the night." ***Patrick Boyle, a researcher in the DCCT.***
- "What's worrisome about these deaths is that they are due to the treatment." ***Philip Cryer, then president of the American Diabetes Association***, referring to the research that shows that between 4% and 13% of insulin dependent people die each year in hypoglycaemic related events.

The Times, October 26 1999

- "The medical establishment doesn't regard what patients say as a valid form of evidence, and that is ludicrous." ***Matthew Kiln, a South London GP specialising in diabetes.***
- "With chronic diseases, when patients depend for their lives on

medicine, they should be made comfortable with their treatment. If two treatments are of equal safety and efficacy, they should be able to choose. There is a danger of not looking at other issues that might be causing hypos." ***Stephanie Amiel, the Professor of Diabetic Medicine at King's College Hospital, London.***

The British Medical Journal, June 19 1999

- "One classic example of cooperation [between primary and secondary care] is the management of diabetes. Monitoring of diabetes can be done equally effectively in primary and secondary care, but the answer is not competition but cooperation, with professionals acting as district wide teams. The primary factor, and the deciding factor, must be the patient. Has the time come for the patient led NHS and the primacy of the patient?" ***Hugh Alberti, lecturer in primary health care and George Alberti, President of the Royal College of Physicians, London.***

The Indianapolis Star, October 31 1999

- "To my knowledge, this is the first time in the history of medicine that a product is being pulled without any consultation with patients and for which there is not a superior (replacement) product. It's an issue that really upsets me." ***Dr Andrew Farquhar of British Columbia.***
- "Animal insulin is the Lindbergh of the space shuttle age, it's antiquated." And that "most people who have problems switching from animal to human insulin haven't tried hard enough to get used to it, or lack guidance on tailoring doses to their bodies and lifestyles. We don't know of a single case where a patient has not been successfully transferred working with a doctor." ***Dr. John H. Holcombe, senior clinical research physician for diabetes care at Lilly.***
- "Hypoglycemia unawareness is not a property of the source of the insulin, those who believe otherwise are "emotional," the science behind them is not there." Dr Bruce R. Zimmerman, president of the American Diabetes Association and a professor of medicine at Mayo Medical School in Rochester, Minn.
- "Animal-insulin users who can't adapt to human insulin often aren't getting the proper professional help. The help of a doctor or nurse is critical because insulin is still a very imperfect drug with a narrow therapeutic window," ***Dr. Alan C. Moses, chief medical officer of the Joslin Diabetes Center of Harvard Medical School.***
- "There isn't much supporting evidence in medical studies that human insulin hides signs of coming hypo. However, there's a ton of anecdotal evidence. We're not making this up. [Many doctors] generally pooh-pooh the whole thing. It's inexplicable. One of the basic tenets of being a doctor is, 'Listen to your patients.'"***Dr Andrew Fahquar, British Columbia.***
- "I've found many children do better on animal insulin, because it lasts longer in their system and is easier to take. We are basically losing a tool that might help us manage the disease in those children. It's like telling a plumber who's come to fix the pipes in your house that he can use only one wrench and one setting." **Dr.** ***Michael T. Swinyard, medical director of the diabetes program at Primary Children's Medical Center in Salt Lake City.***

From the Journals and other sources

- "You can't say 'similar', if it's the same again that you want. 'Similar' means something different…Just as an aquittal for child molesting is not an adequate reference for a job as a baby sitter, so the failure to find a difference [between two drugs] cannot be regarded as proof of equivalence." ***Stephen Senn, The Lancet, Vol 352, July 11 1998:86***
- "He taught me the importance of listening to patients and facing up to mistakes as the only way to devise methods of avoiding repetition." "Remove your wristwatch before seeing your patients." "Be hard on yourself and gentle on your patients and medical staff." " Devote yourself to the fields of your interest, remain deaf to the siren song of mentors, but never lose touch with human emotions." ***Extracts from Lifeline giving advice to newly qualified doctors, the Lancet.***
- "Learning to balance [diabetes] is a developmental process during

which people learn to assume control of their diabetes. Support for such development requires that nurses know their clients as individuals and value the expertise they have gained in living with diabetes," ***Image J Nurs Ach 1998; 30[1]:57-62***

- "The challenge I face [in the transformation from doctor to patient] in getting the evidence I need to make informed decisions is almost overwhelming. I also believe it is my right to determine the value that I place on different outcomes, to express my own treatment preferences [and have these taken into account], and to feel that my treating doctors are prepared to respect my experiences as a valuable and important input when we come to make decisions." ***Professor Chris Silagy, The Cochrane Lecture – 1999.***
- "The new drugs get favourable advance publicity through the popular press, and this tends to distort their actual value, and create a flurry of excitement." Ray Armstrong, University of Southampton, Lancet, Vol 354; Oct 30 1999.
- "This register [of randomised clinical trials] ...might also reduce the risk of abuse to which we drew attention 2 years ago in the description of the premature closure of a clinical trial that involved volunteers, by its industrial sponsors. The event provoked little reaction in the clinical research community. Were we wrong to protest, or have we become so dependent on industrial sponsors that we do not wish to offend them?" Harry Keen, GianoCarlo Viberti, The Lancet, Vol 354: Nov 1999.
- "If human insulin had been named like the previous insulins, it would have been called bacteriological insulin and who would have used it then?" Dr Iain Chalmers, IDDT Annual Meeting 1997.

The final one deserves a place all on its own!

"Historically, improving glycaemic control with soluble human insulin has been associated with an increased risk of hypoglycaemia."

Novo Nordisk, Press release, Sept 9 1999.

Late News

TV in the States

Following the withdrawal of beef/pork insulin in the US by Lilly, November 15th and 16th saw the showing of TV programmes about the whole issue of 'human' v animal insulin. The investigative journalist had done his homework well and even been over to the UK to visit CP Pharmaceuticals – the only possible source of beef insulin for the estimated 100-200,000 people who are now without supplies of the insulin they need. It highlighted the fact that the FDA are insisting on long costly trials before they would give a licence to CP for marketing their beef insulin in the US, despite the fact that they have been producing it for 25years. What better trial could there be than real people actually using it in real life conditions?

The defence for 'human' insulin from Lilly appeared to be 'if these people sneezed three times the day after using 'human' insulin, they would blame it on the insulin.'

The outcome of the programmes was that the studio was deluged with people calling to say 'this happened to my mother, my brother, my sister,' and so on. Yes, we in the UK have heard it all before, but we have to remember that this is the first time there have been programmes like this in the US. Until now it has been hard to reach all the people that may have had or be having problems with 'human' insulin and so it has been difficult to have any sort of united campaign or to assess the scale of the problems. Other channels have said they want to show the programme and so we await with great interest the outcome of this media coverage. Maybe it has to take the actual withdrawal of an animal insulin used by thousands of people to really attract the media coverage that this whole scandal deserves.

Yes, I have used the word 'scandal' because it is just that and if you doubt me just look at a few simple facts:

- Animal insulins are being systematically withdrawn for commercial reasons –synthetic is much more profitable but animal insulins

have not, and never were, replaced by a superior product.

- Insulin supplies are controlled largely by two major drug companies, giving them a monopoly and the power to make decisions about our health on the basis of commercial considerations.
- Large, long-term, double blind randomised trials comparing animal and 'human' insulins have never been carried out, despite all the reported problems. Why not?
- The very early trials showed an increase in hypoglycaemia with 'human' insulin compared to animal, and yet when patients started to complain, they were ignored. Why?
- Doctors have refused people their basic human rights, and in some countries their legal rights, to an informed choice of treatment. Why?
- They have not supported their patients in trying to find out why a sub-group of patients cannot use synthetic 'human' insulin. Why not?
- Synthetic 'human' insulins have never been shown to have any advantages over natural animal insulins and yet have become the insulins that are automatically first line treatment. On what evidence?

What the Papers Say

There has been a lot of coverage in the media about hypoglycaemia unawareness and 'human' insulin and I know many of you will have seen the various articles – The Times, The Financial Times, The Indianapolis Star, Liverpool Daily Post, The Daily Mail, The Mirror and Today on Radio 4 covered it as well.

I genuinely believe that it is sad that we have to resort to the press to draw attention to this whole issue but for years every other reasonable means have been used. When people with diabetes cannot get the insulin they need to remain healthy, as they can't in many countries, when they are classed as 'emotional' or 'anxious' rather than being believed about their problems with 'human' insulin, then they have the support of all of us who live with diabetes. We stick together too and I am afraid that the gloves are off!

A New Fast-Acting Analogue

Admittance that soluble 'human' insulin has been associated with an increased risk of hypoglycaemia

It was the announcement by Novo Nordisk of this new insulin, similar to Lilly's Humalog, that prompted a flurry of excitement in all corners of the world amongst people with diabetes who have been seeking recognition that 'human' insulin causes more hypos and more severe hypos than animal insulin. The key paragraph in the press release from Novo says:

"In long-term, large scale trials, NovoRapid significantly improved glycaemic control compared to that of soluble human insulin and significantly reduced the risk of major nocturnal hypoglycaemia. Historically, improving glycaemic control with soluble human insulin has been associated with an increased risk of hypoglycaemia."

There have been many interpretations of this last sentence but it clearly mentions soluble 'human' insulin when it refers to improving glycaemic control. If it simply means that improving glycaemic control is associated with increased risks of hypos, or even that soluble insulin of any species increases the risks, then why put the word 'human' in at all? Anyway, my reaction is that it is good to know that Novo Nordisk agree with us after all these years! But I do wonder which research they have used to be able to say this and has it been published? Or to be able to say this, are they relying on the reports of patients, the anecdotal evidence, so often dismissed?

Amusement apart, we should look at this seriously and even the first sentence has some meaning:

- NovoRapid has only been compared to 'human' insulin in trials, so while it may improve control when compared to 'human' we do not know whether control would be improved compared to animal insulins. But just how much does it improve control anyway?
- It says that it significantly reduced the risks of nocturnal

hypoglycaemia but does not say whether this is at a cost of higher blood sugars through the night, as has been shown with Humalog. It specifically mentions night time but does not tell us about hypos during the day, were they more or less frequent?

But read on….

IDDT obtained the marketing details from The European Agency for the Evaluation of Medicinal Products and here are some details that may be of interest to you if it is suggested that you change to NovoRapid.

- Two long term open label trials took place with 1070 and 884 patients in each trial. NovoRapid improved HbA1c results by 0.12 and 0.15 percentage points respectively compared to 'human' insulin. **The manufacturers say that this is of doubtful significance.**
- When injected subcutaneously into the abdomen wall, the action of onset will occur within 10-20 minutes of the injection. The peak of action or the maximum effect of the insulin is between 1 and 3 hours. The duration of action is between 3 and 5 hours.
- Transferring to a new insulin should be done under the strict medical supervision.
- There is limited clinical experience in pregnant women – drug company language for 'we haven't tested it on many pregnant women, so you will be a guinea pig.'
- There are no restrictions on treatment with NovoRapid while breast feeding – presumably plenty of feeding mums have tried it.
- It has not been tested in children under the age of 6 years.

All these factors must be born in mind if you are advised to change to this new insulin, especially as the trials show that it does not really offer any improved blood glucose control over that achieved with 'human' insulin. If you have been using animal insulins and your doctor suggests that you change to NovoRapid, you must remember that there is no research to show what will happen, similarly for Humalog, the Lilly equivalent.

"Dead In Bed' Syndrome Is Being Revistied

Most readers will be aware of sudden unexplained deaths that have occurred in people with insulin dependent diabetes – indeed, sadly we keep reading reports of such deaths in newspapers from around the country. The reason they have been classed as 'dead in bed' syndrome is because they all have occurred at night in younger people who are found the next morning in an undisturbed bed. Many of the relatives and those of us who have been involved with diabetes are concerned that these deaths are linked to the use of 'human' insulin – not an unreasonable concern as they did not seem to occur prior to the 1980s when 'human' insulin was introduced. Further to this, in 1991 Tattersall and Gill [ref 1] published a study which had looked at 50 such deaths in 1989. All were using 'human' insulin when, at that time, a higher proportion of people were using animal insulin so it would be reasonable to expect at least one out of 50 to be using animal insulin.

It was assumed that the deaths were related to night time hypoglycaemia. Since 1991, over 80 further deaths of this type have been reported in Scandinavia and it is assumed that nocturnal hypos are the most likely cause.

To our concern we have seen little attention paid to this problem which may only occur in a very small number of cases, but it is nevertheless very worrying and appears to be an upward trend. However, there have been two articles published recently which raise this issue again.

Diabetic Medicine [ref 2]

The authors suggest that 'dead in bed' syndrome probably occurs as a result of undetected early autonomic neuropathy causing heart dysrhythmias [abnormal heart beating] when associated with nocturnal hypoglycaemia. In other words, if someone is susceptible to heart dysrhythmias because of autonomic neuropathy then having a night hypo could lead to sudden death in an undisturbed bed. They go on to suggest that there could well be an at-risk group of people and that in

this group, and especially those known to have autonomic neuropathy, 'nocturnal hypoglycaemia should be avoided at all costs'. They also go on to say that 'dead in bed' syndrome needs an urgent explanation so that possible preventative measures could be developed.

Practical Diabetes International [ref 3]

The authors of this article site three case histories of people who experienced cardiac arrest during hypoglycaemia, one of whom was known to have heart disease. The authors suggest that hypoglycaemia may bring on heart dysrhythmias and that in people with known or undiagnosed heart disease this could cause cardiac arrest leading to sudden unexplained deaths. They suggest that with the increasing efforts to achieve tight control, hypos will be more frequent and this could lead to an increase in the 'dead in bed' syndrome. They also point out that it may only be a sub-group of people who are at risk of cardiac dysrhythmias in association with hypoglycaemia but that this group need identifying. In the meantime, anyone with diabetes suffering cardiac arrest should receive urgent intravenous glucose to treat any possible hypo.

As readers will see, we are actually only one step away from 'human' insulin being a factor in 'dead in bed' syndrome. If 'human' insulin causes more hypos or loss of warnings resulting in more hypos, then there is a greater risk of unexplained deaths occurring. It appears that the 'if' is not really an 'if' any longer because even Novo Nordiask themselves now admit that 'human' insulin is associated with an increased risk of hypoglycaemia [9.9.99], so do the Patient Information Leaflets in both brands of 'human' insulin, so does the British National Formulary etc. etc. It is essential that this whole matter receives further investigation and that all possible risks of increasing hypoglycaemia are avoided. Until the sub-group of people at risk of 'dead in bed' syndrome are identified this has got to include prescribing animal insulins. This may be unpalatable to some healthcare professionals but the evidence is showing that 'dead in bed' syndrome is increasing and this is unacceptable when hypoglycaemia is caused by treatment and not by diabetes itself.

Ref 1 Diabetic Med 1991;8: 49-58

Ref 2 Diabetic Med 1999;16: 626-631

Ref 3 Practical Diabetes Int 1999;16[6]: 189-190

Research - It Confuses Me Sometimes!

I cannot help but wonder if we ordinary mortals function in a quite different way from the people who carry out and write up research papers. I have a real problem sometimes in making the results of the study tally with the conclusions that the authors draw at the end. Let's take an example:

A study entitled 'Patient acceptability and safety of a new 3.0ml pre-filled insulin pen in a clinical setting' was published in Practical Diabetes, May 1999. 74 patients in four different countries completed the study and they used the new 3.0ml pre-filled pen for all their injections. They had all used pens before and the maintained their normal insulin regime during the study. At the end of the study they completed a questionnaire to assess the ease of use of the pen compared to their pre-study method of injecting. Safety was assessed by the number of adverse events, these being hyper- and hypoglycaemia although no comparisons were given for a similar period on their normal system.

Now this is where I have problems!

- The overall ease of use of the new pen was considered to be easy or very easy by 74% of patients although 5.6% found it difficult.
- 54% stated that they would prefer to use the new pen in future.
- 74% said they would recommend the pen to others.

Now when I was at school 54% was thought to be just over half and only just a majority. Call me a cynic but the abstract of the study

concludes that ‘More than 50% said they would prefer to use the new pen in future and 74% that they would recommend it to others.’ Over 50% could mean anything from 51% to 100%. I think this is misleading when the result was actually that only just over half those people in the study would change from their existing system to the new pen, even if this is because people with diabetes are loathed to change, as suggested by the authors. Interesting that there is a gap between those who would use it themselves and those who would recommend it to others – in fact 20% don’t want to use it themselves but would advise their friends with diabetes to do so!!

I feel certain that if it was really superior then the vast majority of the people who had the opportunity to try it, would have said that they wanted to use it in future. In fact, the message I get from this study is that the new pen is OK but only just over half the people who tried it thought it was sufficiently better than their existing pen to bother changing.

So how would I write it up?

The overall ease of use of the new pen was considered to be easy or very easy by 74% of patients with 5% finding it difficult. However only 54% or just over half the patients said they wanted to use the new pen in future.

I think this is fair and not misleading. So having read the study what did I do? I looked at the authors and, guess what, they come from the Lilly Research Team in Surrey and Lilly make the pens! I realise that they have declared their interest but is this enough? I hope the professionals at whom these studies are aimed, read papers like this one with the same sceptical and realistic approach that we ordinary mortals have.

Ghost Writers!

Did you realise that the pharmaceuticals companies employ ghost writers to write up some of their research?

I certainly did not until I read about it recently in an article in the Lancet [vol 354. July10,1999]. The article quoted someone that had been asked to ghost write two reviews under the names of respected authors. This person was given an outline, references and a list of drug-company-approved phrases and asked to sign an agreement stating that they would not disclose anything about the project. They were pressurised to rewrite their drafts to put the product in a more favourable position and shown another company written review as an example. Fortunately this ghost writer asked for a reduction in the fee and told them to get someone else to rewrite the drafts.

- Why do they need to do this and why can’t we have the straightforward facts written up by the people who actually carried out the research?
- Would the straightforward facts not give quite the message that industry wants for their future sales of the product?

Perhaps what is more worrying is that the researchers themselves are prepared to let their work be written up by a ghost writer who may change the emphasis or gloss over some points that may be relevant to the patients who will be using the drug in the future. Being busy people is no excuse for this – if they have the time to carry out the research in the first place then part of that commitment should be to ensure that they write it up and ensure that the facts are presented in their true light.

I used to labour under the impression, as I’m sure do the general public, that a published study was straightforward factual information with no bias and written by the stated authors. It seems to me to be less than honest that people not named as authors should have a significant input into the published study. If ghost writers are employed by the manufacturers of the drug under investigation and the study is

funded by that same manufacturer, this has to mean an even greater degree of scepticism must be adopted by the readers and the public on whom these drugs are going to be used. Added to this, we have no means of knowing which studies have used ghost writers and so scepticism and wariness seems an essential requirement when looking at published studies into new drugs and treatment, especially those known to be funded by industry.

Is there a lesson here in the studies looking into 'human' insulin? The manufacturers certainly had a lot to gain by both its introduction and the defence of it against the criticisms it received when used on large numbers of people. We, the consumers, have a lot to learn but we are getting there. I certainly don't think that people with diabetes that have suffered as a result of 'human' insulin will ever be so trusting again – and with justification.

New Guidance For Doctors In Obtaining Patients' Consent

The General Medical Council [GMC] is the body that regulates doctors and it has issued new guidance for doctors on obtaining patients' consent for treatment. This has to be welcomed by patients because it recognises the importance of information and communication to enable us, the patients, to make an informed choice. Perhaps the crucial statements are:

- 'Patients must be given sufficient information, in a way they can understand, in order to enable them to exercise their right to make informed decisions about their care.'
- Doctors must take appropriate steps to find out what patients want to know about their condition and its treatment.'

Clearly the information doctors will give will vary according to both the patient and their condition but the guidance from the GMC says it may include the following:

- Details of the diagnosis and prognosis [what is likely to happen in the future] –investigations should be made before treatment.
- Treatment options and the risks and benefits of each.
- How and when the condition will be monitored.
- Whether students or doctors in training will be involved.
- A reminder that you, the patient, can change your mind about a decision.
- A reminder that you have the right to seek a second opinion.

It seems to me that the GMC is moving forward looking at it from the patients' viewpoint. Readers will remember that in the past when we have queried why patients have not been given information and choice of treatment [animal or 'human' insulin] we received the standard and irritating answer of 'the doctor has used his clinical judgement and considered that it is not in the patients best interest to have this information'. We even raised this with the Patients' Charter Unit but received little help or understanding.

Perhaps with the new guidance from the GMC doctors will be more willing to give people the information and choice about insulin treatment because if they don't, then they will be flouting their own regulatory body's recommendations – not a good idea and not one that stands up to scrutiny. If for no other reason than this, people do have the right to decide whether to use a genetically engineered product or a natural one and they have the right to know their treatment options and the risk and benefits of each.

Interesting News About Alcohol & Diabetes

To ease your conscientious after the celebrations
The Lancet [July 24,1999] reports on a study looking at the effects of alcohol in relation to coronary heart disease in people with late

onset diabetes.

It has been recognised for some time that moderate alcohol consumption reduces the risk of death from coronary heart disease in the general population by 20-60%. New research from the US finds that a similar but stronger association exists in people with late onset diabetes. In 1984-1986 983 people with late onset diabetes with an average age of 68 years were asked about their alcohol consumption during the previous year. They were then followed up for the next 12 years.

People who had never drunk alcohol and those who had drunk but now abstained had the highest death rate from coronary heart disease. The death rate in moderate drinkers [one to six drinks per week] was significantly lower and even lower in those who had seven or more drinks per week.

Before you get excited, the authors say that they do not recommend that people with diabetes take up drinking for health reasons because the study needs confirming by further research. They also warn that alcohol increases the frequency and severity of

hypoglycaemia and impairs the warning symptoms of an impending hypo. Sorry to disappoint you!

Do You Dabble On The Internet?

If you do you could help to raise the awareness of the problems with 'human' insulin by having your own website. It need not be a difficult task nor need it be a huge impressive site, so don't be put off and read on.

One of our members said that he searched on the internet for information about problems with 'human' insulin and only a few sites were found and so he raised this with us. Quite rightly, he pointed out that the internet is the way forward and is going to be, whether we like it [or understand it!] or not. This is the way many people get their information nowadays. If they only find a few sites that talk about the problems that we know some people have with 'human' insulin, then it gives the impression that it is either only a small problem or that it only affects a few people.

Why this is so important.

1. Those of us that have lived with diabetes for years are aware that there are different insulins – genetically produced 'human' insulin and natural pork and beef insulins and we have had the advantage of being able to make comparisons. But over the last 10-15 years 'human' insulin has become the first line treatment for IDDM and newly diagnosed people are automatically prescribed it and most of them are not given a choice of insulin species. Therefore, they remain unaware that animal insulins exist! If they start to have the classic 'human' insulin problems, where are they going to find out that there are other options and alternatives? Unfortunately they don't seem to be given this information from the diabetes clinics around the country!
2. I know from journalists that have made contact with us that they look on the internet for information and they do like to find personal stories of the issue that they are researching. A one page personal 'testimony' of your experiences with 'human' would provide them with the evidence they are seeking.

- How you can help.

Set up your own website giving details of the problems you had with 'human' insulin. It need only be one page but it will raise the awareness and instead of only a few sites appearing when people search the net for information, lots of sites will appear. Most of all it will be a means of providing information to people who would not otherwise receive it – the people who are being diagnosed now and in the future. If you don't know how to set up a web site but would like to help in this way,

get in touch with me, Jenny Hirst, PO Box 294, Northampton NN1 4XS or tel 01604 622837. I couldn't possibly help, I think I am the wrong generation! But I know a man who can!

Do let us know if you can help in this way or if you are like me and need some guidance with this modern technology.

Unbending Determination

The death of my Dad was a tremendous shock - not least because he was a man who met "triumph and disaster" head on and had resilience and ability to bounce back - no matter what life threw at him. I thought that this time it would be the same but it wasn't.

Since the onset of diabetes in his mid-20's Dad had had many situations which would have stopped many of us in our tracks. Like the change from pork to human insulin which was one of the most frightening things I've ever experienced. Then there was the time he was incorrectly prescribed betablockers and was only minutes from slipping into a coma as he sat at his desk at work. Or how about the time when he suffered a mini occipital lobe stroke two years ago which affected his peripheral vision and robbed him of one of his greatest enjoyments in life – driving.

Dad accepted his diabetes and carried on with his life completely. I don't ever remember him using it as an excuse for anything - to him it was simply "all part of life's rich tapestry" and wasn't something that should interfere with what he wanted to do. Because of Dad's approach to his diabetes, it has always been difficult for me to understand people bemoaning the fact that they or a loved one had diabetes. As children we used to laugh when we totted up how many injections Dad had given himself - he did it all so naturally there was never a taboo or veil over what he was doing. Diabetes was perfectly "normal" to him and thus to us, his family.

Dad was fitter and happier than any of us had seen him in a long time. He'd found new interests in life and was enjoying learning how to "surf the net"…he was due to start a course in September. He'd been eagerly learning the delights of Microsoft Office at another college course - his certificate saying he'd passed arrived in the post a few weeks after his death. He'd joined the new David Lloyd Centre in Nottingham and was keenly looking forward to spending time there getting himself fitter and he'd even booked himself onto a "walking for softies" weekend in the Lake District.

I think if Dad wanted to be remembered for anything it would be his unbending determination not to give in. Whatever adversity life threw at him, he managed, with the help of his loving family, to meet it head on. He never viewed Diabetes as an affliction - merely as part of him - something he respected but not something he feared and CERTAINLY not something that impinged upon his enjoyment of life.

The suddenness and unexpectedness of his death has left a big hole in all of our lives. It's only made slightly more bearable by the fact that he died "living".

He will be missed by his wife, 5 children, 3 grandchildren and all whose lives he touched for many many years to come.

Alison Gordon

2 youngest child of the late Kenneth Francis Gordon ("Ken") "aka Jim – the Midlands"

Jenny Comments – Our sympathies go to Alison and her family. I knew Ken over many years and he did a great deal to help people with diabetes when he was Chairman of the BDA branch in Nottingham. I was delighted when he joined IDDT as an active member, supporting both our annual meetings in Birmingham and contributing to the Newsletters as 'Jim – the Midlands', a title that always amused him.

From Our Own Correspondents

Talking Blood Meters
Dear Jenny,

I have been registered blind since 1978 and in the last three or four years I have lost the minute amount of peripheral vision that I had. I have had a guide Dog since 1978 and am now coming to the end of my second one. I live alone and feel very strongly about the fact that we are unable to obtain 'talking blood meters' in this country.

I purchased one from the US and it is proving quite satisfactory. But the battle to obtain it reminded me of the anger I first felt when I originally bought the meter in the UK. To my amazement none of the instructions were provided in Braille or tape so making it useless. When I complained to the manufacturers they kindly sent me a tape which incessantly referred to the booklet and yet one of the selling points was that it was for use by the blind!

It is well known that blindness can be a complication of diabetes and it seems a disgraceful situation that people like me are unable to easily obtain a meter that they can use and that the only way we can do it is to purchase one from America. Not everyone can afford to do this and there must be suffering as a result.

Mrs MB
South East

Jenny's comments – Mrs MB is so right and her early experiences with no suitable instructions for using a meter designed for blind people shows just how little care or

understanding there is of their needs.
Changing to Hypurin
Dear Jenny,

Thank you for the information concerning Novo's withdrawal of pork Velosulin. With my GP's agreement I changed to Porcine Hypurin and wish to state that I have had no problems since changing. I hope that this will reassure others who are considering the change.

Mr RC
N West

Dear Jenny,

Just a note to let you know that I have changed to Hypurin Bovine Neutral and Isophane because it suited me so well before, but only after a very interesting bit of dialogue! Doctor – "There's no reason why you couldn't go on to beef but there is just one problem – they don't make it any more."

Me, producing a page with all the Hypurin insulins details on it – "Oh yes they do".

The doctor consulted the computer screen and found that they did make it! Surprise. This might be amusing but I am supposed to attend a diabetic clinic where she is part of the team and I can hardly be expected to have very much faith!

Mrs A T
North West

A change with a difference
Dear Jenny,

You will remember that I rang you initially because I was unsure about which insulin to change to after the withdrawal of Novo's pork Velosulin and my chemist had given me one of your 'Caution Notices'. As we were chatting I mentioned that I had always preferred beef insulin because I had better control and more hypo warnings with it than pork, although pork was better for me than 'human'! But I had been told beef wasn't made anymore so I have been using pork. I managed to convince my GP that beef Hypurin is still made and I have now

been on it for a couple of weeks. My blood sugars at first went high, as you said they might, but then they came down to normal – I hate the feeling of being high. I must tell you the differences.

One of the nicest things is that I that when I hypo it is the 'old style' friendly hypo and I have not had such a hypo in 4 years or more. I feel hungry and completely 'compus mentis' even at 3.00 in the morning with a blood sugar of 2.8. It is great because I can deal with it myself. One of the nicest things is that I feel in control again, something I had lost on pork insulin.

Verdict – long live cows!

Mrs W J
North West

Jenny's Comment – This all goes to show that we are all different and we did not have it so very wrong in the good old days when we were encouraged to try different insulins to see which one suited us best.

No Sympathy For The Visually Impaired

Taking Blood glucose meters - Reply From The DoH
Readers will remember reading in the Autumn Newsletter 1999 that IDDT wrote to the then Minister of Health, Frank Dobson, about the lack of availability of 'talking meters' for the visually impaired. Here is the reply from a member of the Health Services Directorate:

'At present there are no requirements regarding the suitability of blood glucose meters for use by the blind and partially sighted. However the Medical Devices Agency of the DoH is involved in the production of an international standard for blood glucose meters.

While this work has not been completed, the draft document states that the meter design [including readability of the results], should address the fact that blood glucose meters are intended for use by users with a broad range of physical and mental abilities. The draft standard also addresses the need for large print in user manuals.'

It is not clear to me what exactly is meant by 'there are no requirements regarding suitability of blood glucose meters' – perhaps it means that this issue has never been looked at. However, I suppose it is useful to know that there are going to be international standards for meters. Maybe it is my usual down to earth attitude but I feel duty bound to point out that for people that are blind, the size of the print in the manuals or the 'readability of the meter' is totally irrelevant because they cannot see!!! I have written a letter pointing this out.

NB. Following this issue being written about in our last Newsletter, we have had several inquiries from Diabetes Specialist Nurses and Practice Nurses wanting information about talking meters to help their patients. Although they didn't understand that they are not available in the UK, this just serves to prove the need. It would be helpful if the medical and health care professionals could raise this matter with government as they are in the best possible position to show the numbers of people that would benefit from this device and the improvements such a device would make to the lives of their patients.

Also Withdrawn From the Market - The Clickcount

These devices were removed from the market in1998 and they were of great assistance to people who could not see well enough to draw up their insulin from a syringe. The clicks enabled them to count the number of units being drawn up. We are receiving inquiries about their availability and the answer is that they are no longer available in the UK but they are available in the US. We are making inquiries from there to see if they are compatible to use in the UK and will let

you know. It does seem that the suppliers of devices for the blind and visually impaired have absolutely no sympathy for this group of people.

Research Grants

It is interesting to read that the Juvenile Diabetes Foundation have made two grants available to Professor Stephanie Amiel of King's College School of Medicine and Dentistry. The first one is 'Investigation of Brain Function and Hypoglycaemia by Functional Magnetic Resonance Imaging' and the second one is 'Mechanisms of Hypoglycaemia Unawareness in Type 1 Diabetes'.

These studies should be invaluable to the future treatment of diabetes especially as we are in a situation where the present day treatment is to achieve near normal blood sugars which research has shown increases threefold the risks of severe hypoglycaemia. We also know from the Novo Nordisk press release [September 1999] that soluble 'human' insulin is also associated with an increased risk of hypoglycaemia.

The results of Professor Amiel's studies should enable people with diabetes to know more about the risks involved of any brain damage from hypoglycaemia from any cause but that we now know can be caused by keeping tight control or by taking 'human' insulin. This will enable people to make a more informed choice of treatment, both about their blood glucose levels or the type of insulin they use – natural or synthetic. Let us hope that Professor Amiel includes in her studies people who use both types of insulin and compares the effects of both. We well remember her talk on hypoglycaemia at our Annual Meeting some years ago when she included the 'human' versus animal insulin debate on her list of topics that were under researched. We await the results with great interest.

After The Battle Is Over - A True Experience

By Rose Jenner

My daughter Frances, as many people will already know through this Newsletter, attempted to bring a test case for medical negligence against our local hospital. Their crime – to put her on to 'human' insulin with no warning of any possible side effects that it may have, or any alternatives that were available.

After a long battle with the consultants in charge of her care, in desperation I sought the advice of Jenny Hirst who at that time had just set up IDDT as a charity. On Jenny's advice, with added warnings of how difficult changing her treatment could prove to be, I sought the help of our GP who was very sympathetic and willing to help. He issued pork insulin with no problems at all, despite being in a difficult position with the local hospital.

Frances almost immediately regained some stability with her blood sugar levels and was set on the road to recovery. A couple of months later we sought the advice of a solicitor and she was granted Legal Aid to pursue a case for potential medical negligence against the hospital.

Two years later, after commissioning a Report by an eminent Professor of Diabetes from a leading London hospital, it was concluded that although Frances had suffered a dreadfully poor standard of care at the hands of the local hospital, and the attitude of the staff left a lot to be desired [it was described at best to be 'cavalier'], the treatment fell short of negligence.

Obviously disappointed at the outcome, we decided that we would 'go public' on TV and to the local newspapers after receiving, anonymously, copy of a report commissioned by the BDA that reported on the adverse effects of 'human' insulin. It was obvious that this had never been made public. HOT STUFF! The Daily Mail ran an article, alongside coverage from our local paper and Meridian TV. We were inundated with calls from people suffering similarly.

However, it doesn't end there. Frances has now become a victim at the hospital now treating her. She was transferred to a well-known diabetes centre thirty miles from our home. Before registering her [we were assisted by our local Community Health Council] we had a one hour interview with the staff who would be treating her [very sympathetic to her case] and also with the consultant in charge. He assured me that he had no problems in treating her with porcine insulin if this was what suited her best.

So what has gone wrong?

His attitude has changed to one of heavy sarcasm and dismissal. He accuses Frances of being 'difficult' and asks if she was always this way. Best of all, he always asks if her mother is in the reception area as he doesn't want me beating down the door if he can persuade Frances to go back to 'human' insulin. This coincidentally happened at the same time as the file arrived from the previous hospital and it also became apparent that he had spoken to the medical staff previously treating her.

One would think that starting as we did with a clean piece of paper at a recommended centre, that her blood results should speak for themselves. Apparently not.

What to do then…

Frances has discussed moving again, possibly nearer, but why should she? She is entitled to obtain the treatment that suits her best, after all, she has to live with it. Changing hospitals will not solve anything if the reputation our local hospital have passed on to Frances is going to follow her around. Frances is the only one who knows how she feels, and I have seen her blossom into a lovely, lively young lady. She has put on weight [when on 'human' insulin she was almost skeletal], her blood glucose control is very good and she has achieved a driving licence and a good job. She has given others the confidence to fight back, as well as providing the information for ammunition to the fight. We have many grateful people telephoning her to say what a difference the change to animal insulin has made to their lives.

The moral of this story – she may not have won this particular legal battle, but she did win her own personal war.

This Patient Does Not Give Consent For 'Human' Insulin To Be Administered

It was very noticeable at the annual meeting in October that a real concern for people was that if they were admitted to hospital for an operation then there was a problem over receiving their animal insulin in a drip and many people had been put on to 'human' insulin. The usual reason was that the hospital did not stock animal insulins. A further point that was raised yet again was that you can argue if you go in for a planned procedure but if you are admitted in emergency then you are not in a position to argue! I have to confirm this because my daughter had to have a Caesarian Section for the birth of her daughter and she was given 'human' insulin because 'the hospital did not have any beef or pork insulin available'. Some people at the meeting felt it was an opportunity used to transfer them to the 'human' insulin that the clinic had always wanted them to be on. Who knows?

There are several points that people using animal insulin need to be aware of if they have to be admitted to hospital:

- Any hospital should be able to get a supply of CP natural animal insulins within 4 hours because it is stocked by all major wholesalers – it requires a phone call on the part of the hospital. Obviously this does not apply at weekends
- You can obtain stickers from IDDT that say the words at the top of this article –

  This Patient Does Not Give Consent For 'Human' Insulin To Be Administered

- If you have these stickers on your notes it is most unlikely that 'human' insulin will be administered should you enter hospital in a condition where you could not speak because anyone doing so would be going against your expressed wishes.

IDDT is considering what action we can take to point out to hospital pharmacy departments that it is quite unreasonable that they do not stock animal insulins. Despite what they might believe there are still 50,000 people in the UK using animal insulin and this is about 1 in 7 of all people using insulin – still quite a large number of people who may at any time need hospitalisation. It surely cannot be beyond their budget to stock a few vials of animal insulins for the occasions when one of those 50,000 people have to go into hospital!

If you would like some stickers for your hospital and GP notes then contact Jenny or Kirsty on 01604 622837 or write to IDDT, PO Box 294, Northampton NN1 4XS

Just To Remind You...

Carer cards
IDDT has Carers Cards for people who are carers to carry with them. Many carers have very real worries that if they have an accident then the person they care for may be left at home unattended. If this is a worry for you then carry one of our Cards. They clearly state that you are a carer and have a space for your name and address and that of the person you care for. The Card says

'Help! I am a Carer. If I am involved in an accident please follow the instructions enclosed.'

These can be supplied to you if you contact IDDT at PO Box 294, Northampton NN1 4XS or telephone 01604 622837

Yellow Cards For Reporting Adverses Drug Reactions

Community pharmacists can now report adverse reactions
Regular readers of the Newsletter will have read about this in previous Newsletters and will forgive me for covering this again for newer readers and members. It is an important way of registering your difficulties or adverse reactions [ADR] with 'human' insulin or any drug, with the Committee on Safety of Medicines [CSM].

The Yellow Card Scheme is the CSM's way of collecting and monitoring adverse reactions to a drug after it comes on the market. Patients are not allowed to report directly to the CSM, something for which patient groups have been campaigning. ADRs can be reported by doctors, dentists, coroners and pharmacists and now both hospital and your local pharmacists are allowed to report. Hopefully this will result in an increase in reporting and you may find your pharmacist more willing or able to actually take the time to report your adverse reactions. This list has also been extended to include nurses, providing the report is countersigned by a doctor! The Scheme is flawed because it is estimated that there is a 90% under-reporting of ADRs but it is the only system we have got. So if you have had adverse reactions to 'human' insulin it is important that you ask your pharmacist, doctor or nurse to report them to the CSM. Only this way will the CSM be able to know that the magnitude of the problems and that they really do exist.

For Parents - Paediatric drug formulary

We previously advised that there was to be a real step forward in information about medicines for children – the production of a paediatric drug formulary. This has now been produced and was launched on July 1st 1999 by the UK Medicines Committee.

To date many medicines prescribed for use in children have not been licensed for children and doctors have had to work out doses from the prescribing advice for adults. 80% of newly developed drugs and 40-50% of commonly used drugs are not licensed for the way they are currently prescribed or dispensed, according to the Chairman of the Medicines Committee in the Lancet [July 10,1999]. 40 reviewers have examined the available evidence about the various drugs when preparing this formulary.

Hopefully this book will be used by all doctors caring for children. Parents should be aware of this when drugs are prescribed for their children and can always ask for more information if concerned about the prescribing of any drug for their children.

Never Carry An Insulin Pen With A Needle Attached

One of our members recently sent us a card she received from Owen Mumford when she ordered needles for her pen. The message is clear:

Never carry an insulin pen with the needle attached and do not replace the pen cap with the needle still attached. If you do the following may happen:

- When you go from a warm place to a cold place the insulin shrinks and air enters the cartridge through the needle. When extra air is in the insulin cartridge your dose may be wrong.
- When you go from a cold place to a warm place the insulin swells and leaks through the needle. If you use intermediate or long acting insulins that contain particles [eg isophane/NPH] the fluid may leak out while the particles stay in and this may change the strength of your insulin.

Parents Part

Depressive symptoms in parents in intensively treated childen with diabetes campared to those conventionally treated.

A study [ref 1] looking at depressive symptoms in parents of children with diabetes treated with intensive therapy [multiple daily injections] and with conventional therapy [twice daily injections] has shown that there is no significant differences in depressive symptoms in parents between those with children treated intensively and those treated conventionally.

The study did not show that parents' depressive symptoms correlated with their child's metabolic control, the duration of diabetes, age of the patient, age of the parent, family size or family income. The authors concluded that switching children to intensive therapy did not reduce the depressive symptoms in parents because in their study there was no reduction in depressive symptoms in the intensively treated group compared with the conventionally treated group. They suggest that because hypos are more common in intensive therapy this may be a source of additional stress for the parents and have psychological effects, so adding to their depressive symptoms.

The reality of what the study shows is that many of the things that were thought to cause parental depression actually don't. It is also interesting because it does show that the depressive symptoms experienced at diagnosis in some parents do not go away as time passes.

As a parent could I dare to suggest that simply having a child with diabetes is something we never quite get over and this is why we show depressive symptoms. May be we don't have to deeply search into why it happens! Let's take a harsh look at the reality:

- Your child is diagnosed with diabetes - a life long condition for which there is no cure.
- You have to face the reality that this is not a condition that even

stays the same – there are always the risks of the complications at the back of your mind.

- You have to live with the day to day worries of bringing up your child with diabetes and keeping the rest of the family happy.
- You have to face the worries of hypos, at night, at school, when they are out socially, when they eventually leave home - this list is endless.
- You feel a huge responsibility for your child's future health and wellbeing and you can never quite get away from the feeling of guilt.
- The longer you all live with diabetes, the more obvious it becomes that the hoped for cure is not around the corner and you even start to wonder whether there is real incentive to find that cure. You question the way in which research money for diabetes is spent.
- It seems incredible that the things that would make life easier and safer for your child, like continuous blood monitoring with warning beeps, are not treated as top priority for research spending.
- We read that the death rates in people with diabetes have not reduced, so we have to question the effectiveness of present day treatment with all the apparent improvements such as home blood monitoring.

Is it surprising that we feel a bit depressed and that this depression is nothing to do with blood sugars, with time, with the age of our children or ourselves, with our income or our family situation? Some of these things may make it worse from time to time but underneath we can never get away from the realities of diabetes. We need to be given some real hope: we need to see that research is going in the direction of making life better for those who already have diabetes as well as research into prevention: we need to be understood and heard and we need to see real progress in the treatment of diabetes for the sake of our children.

Ref 1 Diab Care, Vol 22, No 8 August 1999, 1372-1373

A Word To Parents - Remember You Do Have A Choice

Conventional or intensive therapy for your child

In a recently published study [ref 1] newly diagnosed children with diabetes were randomly allocated to either conventional treatment [1-2 daily injections and 2-4 blood glucose tests] or to intensive therapy [3-4 daily injections 4 blood tests per day]. It was emphasised to both groups that hypoglycaemia should be avoided. The advantage of this study design is that it was possible to know accurately how many severe hypos there were but there was less accuracy of the number of milder hypos because this relied on reporting by the child or the parents.

During the study period it was shown that:

- 6 of the 13 children on intensive treatment experienced severe hypoglycaemia whereas only 1 out of the 12 children on conventional treatment did so.
- The intensive therapy group experienced an average of 85 episodes per 100 patient years whereas the conventional group had 28 episodes.
- The intensive group also had more self reported mild episodes compared to the conventional group, 82 compared to 59.
- During the study period the intensive group had lower HbA1cs than the conventional group 8.26 compared to 9.96%.

Both these groups of children and a control group of non-diabetic children carried out various tests for memory tasks. The results were as follows:

1. The intensive group performed less accurately on the spatial declarative memory tasks [recalling past events] than the conventional group or the controls.
2. They performed more slowly, but not less accurately, on the pattern recognition task than the conventional or control group.

3. In both groups of children with diabetes there was significant impairment on a motor speed task compared to the non-diabetic group.

The authors say that the results indicate that there is selective memory impairment associated with intensive therapy and that this is consistent with the effects of severe hypoglycaemia and medial temporal [area of the brain] damage or dysfunction. They go on to suggest that if similar but larger studies were carried out and showed that severe hypoglycaemia does cause memory impairment then extreme caution should be taken before implementing intensive therapy or very strict blood glucose levels on children with diabetes.

This is where I start to get cross!
The DCCT said this when it was published several years ago! When children are at risk, their future abilities and careers at risk, this research should be top priority – we have already waited too long.

I get cross again!
Journals as far back as the 1930s and 40s contained articles about the damage that hypoglycaemia could cause to the brain.

I get cross again!
There is an editorial in the same journal by Christopher Ryan who is commenting on this study and he says that we should build on existing studies such as the DCCT rather than set up larger studies to look into this because it would be more cost effective. He also suggests that in the meantime we should concentrate on avoiding all risks of hypoglycaemia regardless of whether they are being treated conventionally or intensively. I quote: “This should be done by individualised therapy and more frequent blood tests to reduce the very small risk that diabetes treatment could affect memory and other cognitive processes in the child.”

At this I get very cross!
My immediate response is to ask him to tell us how to do this in our children with all their varying activities, lifestyles, emotions, hormones, willingness or otherwise to follow regimes, do blood tests and injections when they should. A hospital visit every so often to ‘individualise treatment’ is, in some circumstances, as much use as a chocolate fireguard. Clearly he hasn’t brought up a child with diabetes! Would he still be worrying about cost effectiveness and wanting to build on the DCCT with all its inherent now- recognised faults, if his child had diabetes and was running the risks, however small, of impairment that could affect memory and other cognitive processes? I think not! Is the unwillingness to carry out the large much-needed study associated with the risk that it might show that intensive therapy is not necessarily the answer and that treatment regimes of the last few years have, perhaps, not got it quite right?

To all parents
I have to say that the decision about the blood glucose levels that you aim for is a difficult one. We know that the better these levels are, the less is the risk of the long- term complications. But we also can see that there are risks in trying to achieve the targets set by intensive therapy – there is a threefold increase in severe hypoglycaemia and now several relatively small studies have shown the same thing, that there is a risk of cognitive impairment in children. Added to which, no one has mentioned in all this the stress and effects of living with severe hypos where the child loses consciousness, has seizures, is disorientated, aggressive or even violent.

When my child was diagnosed nearly 25 years ago, nobody told me, or other parents, that there were risks associated with severe hypos, maybe they didn’t know, but parents of today do know and so do their children’s doctors. Today, you can make an informed decision, something that was not the case years ago. Discuss all of this fully with your doctors and within your family. It is hard but surely it is something that has to be done. We have to hope that researchers will realise that these decisions have to be addressed by us, the people who live and care for those with diabetes, and we need the evidence from research to help us make informed decisions.

NB I cannot help but add to this article that Novo Nordisk have

admitted that historically, improving glycaemic control with soluble 'human' insulin increases the risks of hypoglycaemia. It has to be questioned therefore whether any child with diabetes should be using soluble 'human' insulin when it has no advantage over animal insulin and it is so vital that hypos are avoided.

Ref 1 Diab Care, Vol 22, No 8, Aug1999, 1318-1324

Another Little Gem!

This time it is an omission and I admit to being a bit naughty with this! I was interested to read in Balance, the BDA magazine, an article for the Millenium picking out the important years in the history of diabetes, for example 1921 being the year of the discovery of insulin, 1980 being the year that home blood monitors became available etc etc. The omission that is glaringly obvious to me is that there is no mention of 1982 being the year that synthetic insulin came on the market! This was supposed to be a big event – 'human' insulin was to be the answer to all our prayers! It was the first genetically engineered drug. It was an exact copy of the body's own natural insulin and would give better control, there would be less antibodies to it etc. etc. It would be cheaper so that even the people in poorer countries would have easy access to it. Clearly with hindsight, the author of the article in Balance didn't even think it was worth a mention!

Hypurin Porcine 30/70 Mix Cartridges

CP Pharmaceuticals announced in November that the re-formulation of this insulin has been successful and that stocks have been released on to the market. In order to be absolutely confident of the product they have tested it throughout six months after manufacture. At no stage of the testing programme has it shown any of the abnormalities of the previous formulation. 30/70 pork pre-mixed insulins are the most widely used insulins in the country and I am sure that users of this type of insulin will be pleased to have the opportunity to try a pen injection device instead of syringes.

As ever, you should discuss any changes from syringes with your doctor. Just an IDDT note of advice – we are used to people who require animal insulins being told that they are not available so go prepared to stand your ground and tell him/her that Hypurin Porcine 30/70 cartridges are available and the manufacturer is CP Pharmaceuticals.

NOTE – If you have any difficulty obtaining supplies of any Hypurin insulins at your chemist, please telephone the Customer Services Department at CP [tel 01978 669272] and let them know so that they can take action. Remember your pharmacy may try one wholesaler and not be able to obtain it and, rather than try another wholesaler, may assume that it is not available.

Response To My Query About Pycnogenal And Its Possible Beneficial Effects On The Development Of Retinopathy

Readers will remember that I printed a short article, entitled 'Are we missing something', in the October 1999 Newsletter. It involved a man in the US who had been using Pycnogenol since the early diagnosis of his retinopathy and some 18 years later his retinopathy has not progressed and he has not had to have the laser treatment that was suggested he would need. I asked if anyone could supply us with more information because several studies have shown its beneficial effects in relation to the blood vessel system in the body.

Our good friend Bruce Beale who organises our web site and has

had diabetes for many years came up with a lot of information for us. But following this so did another of our members. Thanks to them I am passing this on to you because there has been lot of interest from you.

The Story Authentic Pycnogenol ® - from Bruce

Authentic Pycnogenol ® has been studied, actively researched and has scientifically proven its importance in the health of humans for well over thirty years. The historical benefits from this natural phenomenon journey back over five hundred years, originating in Canada. Through the commitment and financial investment of Horphag Research, Ltd., Pycnogenol ® has demonstrated positively, the results of a harmonious alliance between science and nature.

Due to the success of genuine Pycnogenol ®, it is currently copied probably by more wannabe's than any element known. Because there are intentionally deceptive articles, misguided and poorly informed writers, and spurious professionals, Pycnogenol ® has become one of the most misunderstood, misquoted and even misidentified substances seen by the world market. The opportunists who surreptitiously conspire to manufacture counterfeit products have no concern for the public and obviously there corporate goals have nothing to do with health, otherwise they would be following Horphag and spending millions of dollars (as Horphag does) on research, development and new patents. Further, it seems that everyone is attempting to capitalise on the '.ogenol' in Pycnogenol ®. The suffix is now seen on everything from 'hair care, drink formulations to wannabe pine bark manufactures,' looking to jump on the Pycnogenol ® wagon.

Here are the facts:

- There is one company who owns the registered trademark Pycnogenol ® in North America and in numerous countries around the world.
- There is only one company, Horphag Research Ltd, manufacturing the authentic compound and one company selling the genuine raw material, Pycnogenol ®, to the world market.

What is Pynogenal?

Pycnogenol ® is a natural plant extract from the bark of only one species of pine, pinus maritima. It grows along the southwest coast of France, in the Landes of Gascony. Authentic Pycnogenol ® comes from this source and no other. By virtue of this location, where the pure Atlantic Ocean air whisks the moist clean atmosphere across the beautiful Landes of Gascony, the local citizens tell the tourists, "the air here is so clean you can't see it." No pesticides, insecticides, herbicides, foreign or artificial means are used in this area. The trees grow as nature intended them. Slyly, this is not true of other counterfeit pine bark substances. Many are derived from 'Genetically engineered, man made trees. These genetically engineered trees are known sources of serious animal health hazards.

Genuine Pycnogenol ® does not come from any other pine tree bark, grape seeds, grape skin, apple seeds, almonds, pine cones or needles and nor does it come from any other part of the world except the Landes of Gascony, France although very small amounts of it are found in these and other fruits and vegetables.

Pycnogenol ® is unequalled as a natural extract having been obtained from the pinus maritima utilising a proprietary pure water extraction process which provides the purest pharmaceutical grade 100% residue free extract from the pinus maritima. Further to the benefit of the consumer and credit to the substance, Pycnogenol ® has proof of its bioavailability in man.

Clear and expressive findings have shown that only authentic Pycnogenol ®:

1. Slows down the process of decline in the activities of immune and blood generating systems related to aging and restores their functions to normal.

2. Inhibits the formation reactive metabolites of the tobacco-specific

nitroso compound and thus supports a chemo-preventive action against lung cancer.

3. Counteracts the constriction of blood vessels due to stress.

4. Increases human endurance during exercise by 21% providing antioxidant reserves.

5. Improves the morphology of spermatozoa's. The percentage of non-deformed sperms in sub fertile men was increased by 99% after supplementation with genuine Pycnogenol ® for three months.

6. Protects alpha tocopherol in endothelial cells.

7. Inhibits the effects of oxidative stress and minimizes hydroxyl radical induced DNA damage.

8. Is the most potent antioxidant. It provides cytoprotection, produces immuno modulation and strengthens blood vessels. Improves circulation by inhibiting platelets aggregation and induces vaso dilation.

9. Modulates the production of nitric oxide radicals in activated inflammatory cells. Produces beneficial effects in pathologies relating to oxidative stress and inflammatory conditions.

10. Prolongs the lifetime of Vitamin C more than any other flavonoids.

11. Shown to be the strongest hydroxyl and superoxide radical scavenger among all other extracts tested. Is resistant to heat and ascorbate oxidase.

12. Enhances clearance of H2O2 and O2-. Increases the GSH-redox cycle and antioxidant enzymes (SOD &CAT) activities. These antioxidant mechanisms may contribute to beneficial effects in cancer, atherosclerosis, diabetes, ischemia, inflammatory diseases and the aging process.

13. By mouth produces an anti oedema effect. Topical application protects the skin against UV radiation.

14. Protects the retina of the eye against free radical damage.

15. Increases the natural killer cell cytotoxicity.

16. Protects the endothelial cells which line the blood vessels from free radical damage which is considered to be a prime cause for atherosclerosis.

17. Produces vaso protective effect at the capillary level. Decreases oedema and hemmorrhagic tendencies in conditions characterized by increased capillary permeability.

18. Is a safe veno protector. It has been confirmed on the basis of objective and subjective signs and symptoms of static oedema in a double blind study in 40 patients suffering from venous insufficiency.

19. Protects the skin from oxidative stress injury (lipid peroxidation and cytotoxicity). The protective effects were related to dose, with the highest concentration providing the greatest benefits.

20. Increases the pathologically low capillary wall resistance. Is shown to be the most potent among other bioflavonoids tested. Provides strength to capillary walls and makes them less permeable and thus contributes to anti oedema, anti-inflammatory effects.

21. Proven to be the outstanding radical scavenger of enzymatically produced hydroxyl and singlet oxygen free radicals, two of the most dangerous free radicals.

I come back to my original point – shouldn't we be knowing more about this substance if it can do all these things? Can it do all these

things? The answer is that we don't seem to know. Should there not be a review of the science to find out about the effects of this substance and whether people with diabetes would benefit from it? We shall be looking into this further and will keep you posted. It is worth noting that the two people who have looked into this, have both decided to give Pycnogenol a try and they will report back to us.

Update

Pen Needles on Prescription – readers will remember that in February 1999 the government issued a consultation document proposing that pen needles become free on an NHS prescription. Unfortunately this was also linked to the provision of the pens themselves being free on an NHS prescription and the blacklisting of disposable pens ie these not being available on prescription. IDDT responded to the consultation and said that the three items should be treated independently of each other. We also pointed out that pens were already free because they were supplied by industry and therefore there would be a gain for only for industry not patients and the increased cost would be born by the NHS. We supported the blacklisting of disposable pens because it is an unnecessary cost to the NHS and in the few cases where they are essential, they could be prescribed on a named patient basis. At the time of writing this no decision has yet been made and so pen needles still have to be purchased.

GlucoWatch Continous Blood Monitor – this is the non-invasive monitor worn around the wrist designed to take 3 readings of your blood sugar and beep when the levels go to high or too low, these limits being set by the wearer. I am grateful to one of our members who wrote to Cygnus, the company in the US who are producing this device to establish the progress with it. The situation is that Cygnus have done clinical trials in hundreds of people at 15 centres in the US and the FDA has granted the pre-market approval application expediated review status because of its potential benefits to people with diabetes.

- Availability – the company is forming alliances with other companies to licence and market in Europe as well as the US.
- Cost – the pricing strategy has not yet been finalised but one possibility is that the hardware component will be $225-250 [this lasts 3-5years] and the consumable AutoSensor will be $4.00 [this lasts 12 hours after calibration].

Every time there is any mention of this device we receive a lot of inquires about it. Hardly surprising when you consider the differences it will make to the daily lives of people with diabetes and to the risks of future complications. It does not take much imagination to list a few – hypos and all the problems of loss of warnings will almost not exist, driving with diabetes will be far less of a problem, night hypos, unexpected highs will be controlled before they go too high and may be it won't even matter what insulin you use! Its endless and it is hard to accept that this has to be commercially developed rather than treated as top priority research throughout the diabetes associations around the world.

Driving Licence Applications – the new forms for applying and reapplying for a driving licence if you have diabetes have been tightened up even further. Instead of being asked about severe hypos, those that require the assistance of someone else, the forms now ask you to list all hypo attacks even the 'everyday' ones that you handle yourself. Clearly hypoglycaemia is being very seriously watched by the government department responsible for transport.

Thanks To You

On behalf of the Trustees I would like to thank all of you for your continued support for IDDT. We are very grateful to all of you that so generously supported us by renewing your membership and by

buying IDDT Christmas cards. Not only does this help us to continue with our ‘work’ but it also lets us know that we are going along the right lines to support and help you and, of course, to try to ensure that the facts about ‘human’ insulin and the availability of animal insulins, are known.

IDDT – International CURRENT UPDATE ON INSULIN SUPPLIES

AUSTRALIA – Novo Nordisk supplies of beef insulin have now ended and their pork insulin, supplied only on the Special Access Scheme to a very small number of people, appears to be coming to an end as well. Beef Neutral and beef Isophane made by CP Pharmaceuticals are available on a normal doctors prescription but anyone wanting pork insulins will have to go through the personal importation process.

For further information contact CP, details below.

UNITED STATES – at the time of writing [November 99] it is expected that all supplies of beef/pork insulin will have come to an end. CP have been refused a marketing licence unless they go through full and lengthy trials as if the beef insulin they have been producing for 25 years is a new drug. Thanks to pressure from many sources the Personal Importation process has been improved making it quicker, less costly on carrier charges and easier. You can now import 6 months supply, as opposed to the normal 3 months, you do not need a doctor’s prescription but you do need a letter from a doctor to explain why you need beef insulin, that is why you can’t use ‘human’.

GERMANY - we have recently been contacted by a patient’s group in Germany who want to join IDDT-International. In Germany U40 strength insulin has been available but only in animal insulins. This is now under threat of withdrawal and the group are trying hard to stop this so that they can continue to use the insulin that suits them best.

CANADA – The position appears to be very similar to the US and there are discussions taking place to try to improve personal importation for those who need beef insulin. Lilly are still supplying pork insulin but its time is limited. Again we have a contact who wishes to develop IDDT-Canada.

Further information about the importation process can be obtained by looking at CP’s web site http://cppharma.co.uk or contacting CP on telephone +44 978 661261 or fax +44 978 660130

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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From Your Editor – Jenny Hirst

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