Insulin Dependent Diabetes Trust

Report and Accounts

9th October 1999

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The Launch Of IDDT-International

Nearly 70 people gathered in Birmingham for our Annual Meeting, but this meeting was one with a difference – we launched 'IDDT-International' and our visitors came from a far away as Australia, Canada, the United States and Switzerland as well as many of our IDDT members from the UK.

The Toast to IDDT - International

The formation of 'IDDT-International' gives out a clear message that people with diabetes and their families are going to be more in control of their own treatment and the decisions involved with it. This was the toast that was proposed by Jenny Hirst to launch the international umbrella organisation - an essential part of ensuring that we have the information and knowledge to achieve this.

- We will never again be so compliant and accepting of change without question as we were in the 1980s when synthetic 'human' insulin was introduced.
- Never again will we allow the pharmaceutical industry to play one country off against another, as happened in the 1980s – the attitude 'there are no complaints from other countries' will no longer be effective because we shall have our own communication systems.
- Never again will we be so trusting of government health departments and regulatory bodies who licence new drugs and are supposed to carry out effective post marketing surveillance.
- Never again will we make assumptions that the research that is carried out to achieve a marketing licence is sufficient to know that a drug is safe for everyone.
- Never again will we have quite the same faith and trust in the medival and nursing professions that we had prior to the experiences with 'human' insulin.

- Never again will we have the same faith and trust in research – we will no longer accept it at face value.

People who live with diabetes have grown up
Drug companies function on an international level and so do the medical profession, added to which they also have partnerships with each other. These partnerships exclude patients but include an agenda that may well be different from ours.

We have only one agenda: to have the treatment that we need with the species of insulin that suits those needs and to have a safe, long and healthy life.

We know from experience that this can only be achieved by having **information, knowledge, choice and power.** People who live with diabetes have to unite, share their information and knowledge and give a clear message to the drug companies and the medical profession and this message is simple:

- We are not going to go away because we recognise that the experience of living with diabetes is a valuable resource.
- We want our treatment to be based on reliable, long-term, large scale, independently funded trials.
- We want the treatment that suits our individual needs and that recognises that these needs vary in people with diabetes. We want progress so that the range of insulins to suit these individual needs is not reduced but increased with the development of new insulins.
- We want choice and this choice must be an informed one.
- We want natural animal insulins to continue to be available. But probably most of all, we want real recognition that some people are not suited to synthetic 'human' insulin.

Insluin treatment for people with type 2 diabetes

Dr Matthew Kiln
Dr Kiln gave an interesting talk about the treatment of Type 2 diabetes and although all those present had Type 1 diabetes, many of the general points about insulin dose adjustments, exercise and diet were applicable to everyone.

The first treatment for Type 2 is diet and exercise to reduce the chances of heart attacks at a younger age. Anti-diabetic drugs are then introduced if blood glucose levels cannot be controlled by diet and exercise alone. New drugs to help this situation have been developed and they fall into two categories - insulin sensitisers that help the natural insulins in the body to work and also drugs that encourage the body to release its own insulin at meal times.

When is the right time to start insulin treatment?

- This decision is usually taken over a period of several months so that there is time to prepare both the person with diabetes and their families for the change to having insulin injections and all that means for them. People with diabetes and their spouse or partners need to understand the basics of insulin treatment – drawing up insulin, injecting and blood testing.
- When oral therapy accompanied by diet and exercise [where this is possible] fail to control diabetes adequately, then insulin treatment has to be considered.
- There are many things that also have to be taken into account – age and weight, family support and family time, an HbA1c greater than 7.5 [the higher the level and the younger the age then the more likely is the need for insulin], the presence of complications and persisting symptoms of high blood sugars –thirst etc.

Starting insulin treatment

There are two ways:

1. Continuing with oral treatment [tablets] and also introducing a night time injection of a truly long acting insulin. There are few truly long acting insulins left but Hypurin Bovine PZI is available and this has a full steady 24 hour action.
2. Twice daily injections of premixed insulin. The premixed animal insulins have a gradual smoother action and are often preferable for people with Type 2 diabetes. Elderly people are often best suited to beef insulins because the peak of action is smoother than both pork and 'human' insulins and so they are safer because there is less likelihood of hypos.

Changing the dose

Dr Kiln gave some tips that apply to people with both Type1 and Type 2 diabetes:

- Once stabilised try not to change the dose too often
- People can end up on too much insulin – both doctors and patients are probne to increasing the dose but rarely reduce it.
- Occasional high blood sugars can be treated by increasing exercise, drinking more and adjusting the diet at the next meal instead of increasing the insulin dose.
- A general rule is that the dose should be high in the morning and low at night.

Dr Kiln ended by saying that the treatment of people with diabetes was increasingly less hospital based, especially for type 2 diabetes and doctors must consider the action times of the various insulins.

Driving and hypoglycaemia

Professor Arthur Teuscher, Switzerland
Professor Teuscher reminded us that he had been involved in the treatment of diabetes for 45 years and with the issue of insulin for the last 20 years. He also reminded us that there had never been a prospective double blind study comparing animal and 'human' insulin, probably the first time that a vital new drug had not been tested in this way. With some amusement he described the widespread use of 'human' insulin without such studies as being due to 'enthusiasm'. He pointed out that the reasons for raising the issue of 'human' insulin in relation to driving was because some patients reported that they had more hypos and less warnings of them when using 'human' insulin and this raises issues of safety when driving.

Some quotes and facts

- 1 in 300 drivers have diabetes – S Amiel, Diabetes Medicine April 1999
- MacLeod in Diabetic Medicine, April 1999 said that there were more hypos in drivers using insulin during the late 1980s but concluded that there was no good evidence to relate this to the increasing use of 'human' insulin. He said that it was due to either incorrect diet, not testing enough or exercise without reducing the insulin dose.
- In Quebec statistics show that in Class 3 truck drivers with diabetes, there is a 2.3 increased risk of hypoglycaemia being the cause of accidents.
- An article in The New England Medical Journal, January 3rd 1991, concluded that there is a slightly increased risk of accidents in people with diabetes and epilepsy.

Professor Teuscher pointed out that the problems are always blamed on the patient and never on the product. He reiterated his belief that where 'human' insulin and hypoglycaemia are concerned it is a product problem and not a patient problem! To demonstrate this point Professor Teuscher showed the press release from Novo Nordisk, dated September 9th 1999:

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

Professor Teuscher then explained that he had researched the road traffic accidents involving people with diabetes in Zurich between

1993 and 1998 and compared these to the decreasing use of animal insulins or the increasing use of 'human' insulins.

Year	1993	1994	1995	1996	1997	1998
Number of accidents	5	6	10	12	13	13
Animal insulin use	20%	17.8%	15.4%	13.6%	11.7%	9.8%

This chart shows a marked increase in the number of accidents over the period that the use of animal insulin decreased. Professor Teuscher also noted that on the ranking for motor accidents in people with diabetes, hypoglycaemia was the largest single cause and many of the other causes - such as falling asleep at the wheel could also be due to hypoglycaemia but not classified as such. He emphasised the importance of the need to take precautions while driving and the advisability of driving when there warning symptoms are reduced or absent.

An encouraging note for us all, as consumers, concluded Professor Teuscher's talk to us.

He quoted from an article by Maria de Alva, President of the International Diabetes Federation, who is not a physician but is a consumer - she has diabetes. She says,

"In most healthcare systems there is no recognition of the capabilities or expertise of the consumer, while the physician frequently regards himself as the only trained member of the physician/patient relationship. Give this scenario, it is natural for the healthcare provider not to consult the patient. Further, diabetes education is often given only to enable the person with diabetes to follow instructions and not to empower him to take decisions. All this gives rise to consumers who are passive, fragile and extremely dependent.

These traditional roles account for the dependency of a lay person and the paternalism of a physician. It creates resentment and frustration when an assertive and knowledgeable lay individual does not behave 'traditionally' and questions a healthcare provider… This traditional relationship often continues within a diabetes organisation, and causes its failure.

People with diabetes and healthcare providers have to dispose of the roles they have played for centuries and start acting as equal partners when they work together in a diabetes association."

"She'll Be Right, Mate"

Larrane Ingram, Australia
Firstly Larrane explained the position in Australia because it is different from that in the UK and the USA.

- 'Human' insulin was first introduced at the beginning of 1990.
- Everyone using insulin was changed almost overnight from their natural animal insulin to the highly promoted 'human' insulin. The promotion was very successful at the time and we believed that all we were told that this wonderful 'human' insulin had real benefits and it would make all other insulins redundant.
- The words "GENETICALLY ENGINEERED or BIOSYNTHETIC" were omitted.
- Doctors, diabetic educators or people with diabetes did not question the validity of the claims about this wonderful new insulin and nor did anybody question the withdrawal of animal insulins.
- Novo Nordisk removed their porcine insulin from the market very speedly after the introduction of 'human' insulin – presumably so there was no way we could go back! But their bovine remained available until August 1999, when that too was removed.

Larrane's Experience: Personally, I was very enthusiastic about the change and the better quality of life being offered by the new 'human' insulin. Even as I started to become increasingly unwell and susceptible to every minor infection, I accepted all the explanations offered by the medical professionals. Finally, after 18 months on 'human' insulin, I found myself in hospital with unexplained sceptecaemia. Only then

did I start to realise that things were not right and looking back at my blood glucose results, it was clear that it all began when I changed to 'human' insulin. I think this is what the professionals call – anecdotal!

In the lead up to this final hospitalisation I had:

- Lost my independence owing to the sudden onset of hypos making it very risky for me to drive myself.
- Had unexplained weight gain.
- Extreme mood swings.
- Constant 'flu symptoms leading to 6 months off work.

With the support of my GP and a consulting specialist in 1991 I was returned to Novo Nordisk porcine insulin on the Special Access Scheme [similar to your named patient basis for obtaining unlicensed drugs]. However, this only applied to a small number of people and no one has been added to this Scheme in recent years. In 1998 I received a letter from Novo Nordisk suggesting that I change to an alternative insulin because porcine insulin is in short supply. After desperate and frantic enquiries I made contact with Jenny Hirst and IDDT in the UK and light was cast on the evolving story.

The situation today:
The promotion of 'human' insulin in Australia today is still strong and successful - most newly diagnosed people do not know that any animal insulins are available or that there is even an alternative to 'human' insulin. Once 'IDDT – Australia' was formed we found that CP Pharmaceuticals had had a marketing licence for bovine insulin for many years. It is available on a doctor's prescription and through our Pharmaceuticals Benefits Scheme. Most people in Australia have been unaware of this, assuming that when they were told that animal insulins had been withdrawn that this applied to all animal insulins. In reality, it only applied to those made by Novo Nordisk but patients were never told this and they were denied their right to choice.

Those who need porcine insulin can import it on a personal basis from CP Pharmaceuticals in the UK but this is expensive and for many people this cost is prohibitive.

IDDT-Australia has targeted letters to the editors of local papers and the major Sydney papers but as a very large country we are divided into 7 States with no real national media as you have in the UK making communications more difficult. Nevertheless, we have had a steady stream of letters of phone calls, letters and faxes from very worried and, some very desperate, people with diabetes wanting more information about the availability of animal insulins. However, the majority of Australians once they received the information from us had the typical laid back attitude of "She'll be right now mate, I've got my insulin."

From 1991 in Australia we have been misled and misinformed about the availability of animal insulins and, to be fair to the medical and nursing professions, so have they. This has not changed and, as a result, since Novo Nordisk's recent withdrawal of bovine insulin, many people have been told that they will have to use 'human' insulin even though bovine insulin is available from another manufacturer!

Larrane concluded by giving us some disturbing quotes from the correspondence she has received:

"If animal insulins are to be discontinued, I would rather not live."

"I have been told by my doctor that the problems I have been experiencing with hypos and general ill health, are all my own fault for not controlling my diabetes properly."

She ended with an encouraging story that is very familiar to many of us:

A Mum rang IDDT-Australia about her 15 year old son who had been taking 'human' insulin for 5 years. He was moody with a general feeling of ill health and daily severe hypos. She decided that she should try to obtain bovine insulin for her son. The first specialist turned her down but she did not give up and had success with a second one. She rang

some weeks later, very grateful to IDDT because for the first time in five years her son felt he had got his life back – an expression so often used after a change to natural animal insulin.

The American Way

Robin Harrison, USA

Again Robin described her personal experiences and the situation in the USA. Robin's experiences are particularly interesting because she is one of the people that those who are sceptical about the problems with 'human' insulin causes, prefer to think do not exist! She had problems with 'human' insulin but had not previously used animal insulins, showing what we know to be true – that the problems do not just occur in people always used animal insulin.

Robin said that when diagnosed she was prescribed 'human' insulin automatically. When she suffered hypoglycaemia with no warnings and severe hypos leading to sudden unconsciousness she realised that she could not continue a normal life looking after her children. Through contacting people on the internet she realised that others had gone through similar experiences. She also discovered that there were alternative insulins – natural animal insulins. The change to beef/pork insulin improved her life beyond belief.

The situation in the US:

- Eli Lilly introduced 'human' insulin into the US in 1982/83 and people were gradually transferred to the new insulin and the newly diagnosed were automatically prescribed it. Novo Nordisk has a much smaller share of the market for insulin sales than Lilly.
- In 1992 there were 30 different insulins available for individual needs and in 1999 there are only 10 insulins left – pork and 'human'. Unlike the UK the majority of people using animal insulin in the US use beef insulin.
- In 1997 we read that Lilly intended to withdraw the only beef insulins left on the market as Novo Nordisk had already withdrawn theirs. The formal announcement was made in late 1998 with a statement that 'people could be safely transferred to 'human' insulin.' Despite the fact that many of us know that we cannot use 'human' insulin because we have already tried.
- In 1999 we have only 10 insulins left because the drug companies have systematically withdrawn animal insulins, so we are left with a choice of 'human' and pork. Pork does not suit everyone and anyway we have little faith that supplies if this have any long term future.

- There is a debate about the number of people affected by the withdrawal of the insulin that suits them best, Lilly maintains that this is a small number but even their estimates vary but they have said it is 6% of people using insulin. In a country the size of the US this is 200,000 people that are going to be left without the insulin that they need to manage their own condition. In the States we have always believed in the free market and the restrictions on insulin supplies seems to be against this principal. Insulin is not a luxury but supplies are being controlled by the fact that there are only two major suppliers.
- Robin pointed out that the American Diabetes Association has not offered any support to patients needing beef insulin nor has the medical community been supportive. The FDA, the US regulatory body, has appeared not to be aware of the problem until recently. They have no powers to force the manufacturers to go on producing beef insulins but recently due to pressures to improve the personal importation programme so that we can import beef insulin from CP, the FDA has issued statements that beef insulin is medically necessary. Thanks largely to the efforts of Charles Savage and the team at CP
- we can now import 6 months supply rather than the normal 3 months,
- the process has been speeded up
- no prescription is necessary although we still have to have a letter from a doctor to say that we need beef insulin and cannot use 'human' insulin.

I, and the many people like me in the US who need beef insulin,

welcome the formation of IDDT-International. We need to unite to ensure that people with diabetes choice and the insulin that they need wherever they live and we need to ensure that their lives are not ruined by unnecessary severe hypoglycaemia without warnings.

What The Text Books Don't Tell You About Diabetes

Dr Laurence Gerlis

Dr Gerlis in the relatively short time that the meeting allowed covered many aspects of diabetes, the realities and ways of living with it. His main points were as follows:

'Human' insulin

- There is not a shred of evidence that shows that 'human' insulin has any benefits over animal insulins.
- Both the data sheets for 'human' insulins manufactured by Novo Nordisk and Eli Lilly include statements that there is increased risks of hypoglycaemia and unawareness with 'human' insulin.
- The dismissal of patients' reports of problems with 'human' insulin because this is 'only anecdotal evidence' is quite wrong – all reported side effects for any drugs are always anecdotal.
- The demand for scientific evidence to prove that these side effects exist, is unrealistic because it is impossible to prove a negative.
- The 'dead in bed syndrome' does occur in people using 'human' insulin and Dr Gerlis emphasised that these are avoidable deaths that should never happen.

Living with diabetes - Dr Gerlis reminded us of some of the things that must be remembered and some of the myths about diabetes

- At diagnosis the thought of having to have injections forever clouds everything else and people cannot learn very much about diabetes at this stage.
- That increasing the number of injections does not mean that diabetes has 'got worse'.
- That if diabetes is looked after properly then you can live a long and healthy life.
- That this can best be achieved by a regular lifestyle – regular eating patterns and regular exercise, regardless of the so-called freedom that multi-dose regimes can offer.
- That young people with diabetes want to do what their friends do but the reality is that with diabetes, they cannot always do this. They cannot get drunk, take drugs and stay in bed until 2.00 in the afternoon. It is no good being shocked at this statement, the facts are that alcohol and drugs are readily available and these issues must be faced and discussed with young people with diabetes.
- Both alcohol and insulin are potent and powerful and they have to be treated with respect. Alcohol not only lowers the blood glucose but also masks the warnings of hypoglycaemia and this is a dangerous situation. Hypo warnings can be missed and hypos can be misinterpreted by other people – so that people may appear to be drunk.
- Both doctors and patients tend to raise the dose of insulin and rarely lower it. If the high blood sugars are the body's reaction to a hypo in the night, for example, then raising the insulin dose will only make this situation worse and leads to a vicious circle of increasing doses to cope with highs, leading to more hypos and so it goes on.
- Dose changes should be made in only 1 or 2 units at a time.
- Dose changes should be kept to a minimum by altering the amount of exercise and the food at the next meal to cope with the odd high blood sugar.
- There is nothing wrong with what is called conventional therapy, twice daily doses of short and longer acting insulins, and it is quite possible to achieve 'good' control on this regime.
- Insulin is a delicate protein and small but subtle changes in the insulin molecule, such as the difference between the insulin molecule in pork and 'human', can affect diabetic control in some patients.

Dr Gerlis ended with one very clear message for us all, one that applies to life in general but especially appropriate to all those with diabetes:

“What we do today, always impacts on tomorrow.”

Discussion and question time
This was the time towards the end of the day for a lively discussion from the audience and the opportunity to highlight issues raised during the day. The key points were:

Animal insulin supplies in hospitals

Many people expressed real concerns about there experiences of being an in-patient and being told that they could not have animal insulin during their operation, usually because the hospital didn’t stock it. If you entered hospital in emergency then you are in no position to argue. Some people felt that a hospital stay was treated as the opportunity to be able to change this ‘non-compliant’ patient to ‘human’ insulin.

- It was agreed that IDDT should take action directly with hospitals to try to influence this situation, reminding them that 50,000 people still use animal insulins – not an insignificant number. This is 1 in 7 people with diabetes who could enter hospital at any time.
- It was pointed out that all major pharmaceutical wholesalers in the country stock CP Hypurin insulins and they should be available to any hospital within 4 hours, except at weekends.
- IDDT does supply stickers to people with diabetes concerned about this, for hospital and GP notes. The stickers ‘This patient does not consent to the administration of ‘human’ insulin.’

Misinformation about availability of animal insulins
Real concerns were expressed that there was a great deal of misinformation about availability of all animal insulins in both vials and cartridges amongst professionals – doctors, diabetes specialist nurses and pharmacists. This can be embarrassing for patients and means that they have often to be assertive in order to obtain the prescription they need. It was agreed that:

- IDDT would encourage people to let CP Customer Services Department know when these problems arose at the pharmacy so that they could follow this up.
- IDDT should wherever possible provide factual information to patients to take with them.
- IDDT should continue to take every opportunity to make it known to professionals that natural animal insulins are available and that some people are better suited to them than synthetic ‘human’ insulin.

Joint pains and swellings with ‘human’ insulin
Discussion on this topic was lengthy and notable because it has not come up at other IDDT meetings in a significant way, even though it was a clearly defined symptom category in our initial questionnaire about the problems encountered with ‘human’ insulin.

- Many people present had found that they had been treated for arthritis or rheumatism but had found that these symptoms had disappeared after a change [for reasons other than this] to natural animal insulins.
- One person who had recently tried ‘human’ insulin again had immediately experienced an increase in joint pain and swelling – this had happened to him in the 1980s when he was first given ‘human’ insulin.
- This provoked other participants, still using ‘human’ insulin, to recount their joint pains and swellings, not surprisingly, something they had never thought could be related to ‘human’ insulin.

Dose adjustments made too frequently

Both Dr Gerlis and Dr Kiln emphasised the need to not increase doses of insulin too frequently and when doing so to only make the increases by 1 or 2 units at a time. They also highlighted the need to remember that it is better to take some exercise or reduce the carbohydrate intake at the next meal if the blood glucose levels are high. Participants who had a long duration of diabetes commented that:

- this was the way they were taught years ago and it was easier to keep a more fixed dose and vary diet and exercise in order to keep good control.
- The multi-dose regime encouraged people to keep changing doses and then there can be too many variables involved to achieve stability.
- The need to recognise that there is always a tendency for both doctors and patients to put insulin doses up to cope with high blood sugars without looking at the causes of the highs. These may be as a result of a hypo in which case putting the dose up is the opposite of what is needed.

Hypoglycaemia without warnings

The following points were made:

- There needs to be a greater understanding by professionals of the effects of hypoglycaemia generally but especially when there is partial or total lack of warnings.
- There needs to be greater understanding of the effects on carers and other family members and on family and marital relationships.
- If this was understood, then professionals would take every opportunity to minimise these by being more willing to believe patients, the BNF, the data sheets and now even Novo Nordisk themselves when they admit that improving glycaemic control with soluble 'human' insulin increases the risks of hypoglycaemia.
- That there is a need to convince healthcare professionals and doctors that if a person is experiencing frequent and or severe hypos or any other unexplained symptoms, then they should try natural animal insulin.

IDDT Annual General Meeting

The members approved the minutes of last years AGM, the Annual Report of the activities of the Trust and the Audited Accounts.[Copies are enclosed with this Newsletter for members]. Our Treasurer, John Hill, pointed out that 1998 had been the turning point for IDDT because we had moved from the position of wondering if we could afford the next postage stamp to a much more secure financial future thanks to generous legacies from both members and non-members. This growth has continued through 1999 and it has enabled the Trust to be in a position where:

- We could initiate activities.
- We could afford to increase our mailings to increase the accessibility of information to people with diabetes.
- We could really concentrate on consolidating our plans to move forward to try to ensure that people with diabetes have a choice of insulin treatment to suit their individual needs, wherever they may live, and that natural insulins remain available to provide that choice.

The meeting then continued and Jenny Hirst and John Hill were re-elected to as Trustees of IDDT.

Any other business.

The problem of hospital pharmacies not stocking animal insulins for people entering hospital either in emergency or for a planned operation was raised – the usual reason for this being given as 'animal insulin is not commonly used'. The problem appears to be of real concern when an insulin drip is required because for other circumstances people take in their own animal insulin. The additional problem of people being changed to synthetic 'human' insulin while in hospital, even sometimes without their consent because they were actually unconscious on admission, was also discussed. It was agreed that IDDT should take positive action on this issue to try to ensure that this situation is rectified. The AGM was formally closed and the interesting part of the day commenced.

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