Insulin Dependent Diabetes Trust

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IDDT - A Maverick Organisation!

Recently in the nicest possible way, IDDT was described as a something of maverick organisation! If being concerned about the future of people with diabetes and their families who can't use synthetic or 'human' insulins, then yes, we are a maverick organisation. If openly facing the realities of the influence of the pharmaceutical companies on all our lives, then yes, we are a maverick organisation. If being one of the few medical charities with a declared policy to not accept any pharmaceutical funds so that we are, and are seen to be, totally independent and uninfluenced, then yes, we are a maverick organisation. If publishing a straightforward 'upfront' newsletter makes us a maverick organisation, so be it!

This maverick organisation was formed In 1994 by six people with very specific aims:

- to seek recognition of the adverse effects of synthetic 'human' insulin in some people
- to listen, to help, support and inform people with diabetes and their families who experience these adverse effects
- to ensure that people with diabetes have an informed choice of treatment
- to ensure ongoing supplies of natural animal insulin
- to represent the needs of people with diabetes wherever possible.

Some nine years later, the six people have multiplied and not only have we increased our UK membership, but we have IDDT groups and members in many countries around the world. So we must be doing something right! Only our members can truly tell us what it is, but I like to think that it is because we have remained focussed

on our original aims. We have expanded our areas of interest and we provide information about a wide variety of topics related to diabetes, but our core focus remains the same, people with diabetes must be informed in order to be able to make choices about their treatment options.

To make choices about our healthcare, we need to be aware that some sources of information may be biased by sources of funding. Some information, even from healthcare professionals, is inaccurate or even wrong - *"animal insulin is not available in pens"*! We need to aware that an absence of information is a form of bias and that research, an area that we ordinary mortals believed was a world of total respectability, can also be biased and influenced by funding.

Perhaps what makes IDDT something of a maverick organisation, is that we openly recognise that we only have choice, if we are fully and correctly informed and all too often, we are not. We are entitled to an informed choice of treatment and we deserve an informed choice of treatment but all too often, only lip service is paid to giving people with diabetes this informed choice.

A maverick article suits a maverick organisation!

The Business of Diabetes - Clinical Diabetes 21:40-42,2003
This paper written for physicians by S B Leichter, MD, highlights just what a commercial product insulin really is. It points out that the trend for manufacturers to see insulin as a growth potential has increased over the last 5 years with the introduction of insulin analogues and novel injection devices. More importantly the author points out that although these innovations have been presented as improved medical therapy, it is the business rewards [read profit] that are the drivers of these developments. He questions whether the clinical benefits [read control of your diabetes] of the newer insulins and delivery devices justify the increased costs. While this paper is written about the US situation, it must not be forgotten that our NHS system has to pay for or 'free' insulin in the UK.

Each one more costly than the previous one and for what benefit?

- In 1982 'human' insulin came on the market, with promises of cheaper and never ending supplies. It has never been cheaper than animal insulins and as we know, in developing countries is unaffordable for many people.
- Then came pen injection devices with the same insulins costing significantly more per unit than when in a vial! And even more expensive per unit in pre-filled pens!
- In the mid 1990s analogue insulins, so-called designer insulins, appeared on the scene, again with a significant price per unit increase over their predecessors. In the 21st century we are now seeing long-acting analogues being the 'in thing' and certainly in the UK, Lantus is even more expensive.

What are the benefits for patients?
The paper says *'the justification for the cost of these newer insulin products, based on their demonstrated clinical efficacy, remains to be completely confirmed'.* Polite way of putting it, as it goes on to say:

- In each case whether for insulin analogue or the pen injection device, there are no large-scale multi-centre studies documenting that the new products provide any meaningful improvements in HbA1cs.
- In detailed studies of Lantus, even though there is less variation in blood glucose levels over time, no study has yet clearly shown that Lantus reduces HbA1cs more than isophane or lente insulins.
- In studies of short-acting analogues, Humalog and NovoRapid, even though they have been shown to lower postprandial [after meals] blood sugars, it has not been demonstrated that they lower HbA1cs more than previous soluble, short acting insulins.

On the positive side the paper says 'the literature does provide fairly convincing evidence that analogues are associated with moderately lower risks of nocturnal hypoglycaemia than the equivalent human insulins'. It also makes the very justifiable point that if patients prefer pen injection devices, then this may improve their acceptance of

insulin therapy and reduce hypoglycaemia.

What benefits have the last 20 years of insulin developments bought for people with diabetes? *Not many, has to be the answer to this.*

What benefits have the last 20 years of insulin developments bought for the NHS and other healthcare systems? *Just increased costs.*

What benefits have the last 20 years of insulin developments bought for the insulin manufacturers?

In the last financial year worldwide:
Lilly - $1.2 billion annual sales
Novo Nordisk - $1.9 billion annual sales
Aventis - $250 million annual sales
Expected growth in the market of 10% per year

Should cost influence prescribing?
Obviously the paper says that business or economic costs will not and should not be the sole or even the prime basis for the selection of insulin therapy. However 'cost should be a criterion in the treatment design' and 'certainly a theoretical relationship between cost and clinical efficacy constitutes some valid basis for the selection of treatment'.

Yet another IDDT maverick comment to this would be to point out that in the UK NHS system we have NICE, the National Institute for Clinical Excellence. Its role it is to assess treatments and drugs both from the point of view of their performance, risks and benefits, and their cost effectiveness. It seems that all the evidence suggests that the last 20 years developments in insulin have provided very few benefits for the majority of people with diabetes but the costs to the NHS and therefore the taxpayer, have increased very considerably. A further maverick comment has to be that we are forever hearing about the huge costs of diabetes care and we are seeing blood glucose reagent strips being denied or restricted to people in some areas. Yet no one seems to look at the prescribing of 'modern' insulins at the very significantly increased costs that cannot be justified on the basis of evidence of benefit. Is this sacred territory?

IDDT Annual Meeting

IDDT's Annual Meeting and AGM will take place October 11th and 12th in Birmingham so put the date in your diary. As usual there will be interesting speakers, plenty of discussion time and for meeting other people with diabetes and their partners. Members will receive further details in August.

Should I Apologise For The Dept Of Health?

By Jenny Hirst

In the front page article of the April 2003 Newsletter, I welcomed the advent of patients being able to report suspected adverse drug reactions [ADRs]. Despite patients reporting to NHS Direct and not directly to the Committee on Safety of Medicines, I looked upon this as a real step forward in improving the evidence about suspected adverse reactions and therefore improving the safety of the medications we take. My reasons were simple - as there is an estimated ADR underreporting of 90% by doctors, this change should result in ensuring our adverse experiences are actually reported and we would no longer be relying on our doctors to believe our adverse experiences.

I even went so far as to announce that this was going to happen in February 2003! I went on to encourage readers who had experienced adverse reactions when using synthetic insulins, to report these to NHS Direct.

Silly me! I thought that this was actually going to happen because I believed the announcements by Lord Hunt, the then Minister of Health and articles in the medical and lay press articles! When people followed my advice and phoned NHS Direct - they knew nothing whatsoever about this new system.

Egg on my face? I'll let you be the judge. I contacted NHS Direct, who could only supply me with information I already had from Lord Hunt. I then wrote to the Medicines Control Agency, now the Medicines and Healthcare Products Regulatory Agency [MHRA], to ask for clarification and to question how the system will actually work in practice. I received a reply but believe it or not, it's got **'CONFIDENTIAL'** at the top! So although I wrote as your Chairman, representing IDDT members, sorry, but I can't tell you what the response was! So I wrote back to ask if they would like to issue a response that I can make public.

I received a reply and I am allowed to tell you that on April 25th, the new Health Minister, David Lammy, announced that the first phase of patient reporting of suspected adverse drug reactions via NHS has started in South East London at the NHS Direct Centre based in Beckenham. Subject to experience at this centre, the intention is to roll it out to all 22 of the NHS Direct centres in England. However, I am not allowed to offer an explanation about the February start date but I will tell you that the system was supposed to start in February 2003, so the information I gave you was correct. Forgive my sarcasm! But what other way is there to handle such a ludicrous situation especially when we are supposed to have open government.

Suspected adverse reaction reporting is important!

It is also important that information about the reports is made much more accessible to everyone but especially the medical profession who are responsible for prescribing and for providing us with an informed choice of treatment, including risks and benefits. This letter from one of our members says it all:

'I was diagnosed in 1982 and for many years my diabetes was controlled by tablets. Then a few years ago the doctor advised me that that I would have to start injecting insulin.

I was not told there was any alternative to the human insulin he prescribed and I began injecting myself three times a day. As time went on I found myself getting depressed and lethargic with no will or ambition to do anything. I would often have mood swings, sometimes becoming aggressive for no real reason. Then one day my wife read an article in the Guardian which described my symptoms exactly. The article was about diabetics on human insulin and the side effects they reported were just those I had suffered for years. According to the report the sufferers were changed to animal (pork) insulin and their worrying side effects disappeared.

I went to my doctor as soon as I could get an appointment, armed with the article and asked to be put on pork insulin. My doctor read the article with apparent amazement and said he had not been aware of the reported side effects of human insulin. However, he prescribed the pork insulin as I requested and the transformation in myself was almost immediate and dramatic. Within 24 hours my wife said there was an improvement in my character and I can honestly say I began to feel so much better in myself within days. I look back on those years on human insulin and feel that the medical profession let me suffer without even advising me that I might be subject to such severe side effects. Some days were so bad and I was so tired that it made me feel suicidal. If my wife had not seen that article and I had not changed to pork insulin I hate to think how I would have managed.

It's not right for the medical profession to treat the public this way. Adverse drug reactions are one of the biggest killers of the 20th century and something must be done now.'

Mr F.R, West Midlands

Frequently Asked Questions

Where can I get an identity tag giving my medical details? Medical-Alert bracelets and necklets from MediAlert on FREEPHONE 0800 581 420 or visit their website www.medicalert.org.uk Or there are Medi-Tag bracelets and pendants from Hoopers, Medi-Tag phone 0121 200 1616

Where can I obtain more information about the GlucoWatch Biographer that provides non-invasive glucose readings for up to 12 hours? FREEPHONE 0800 028 5256 or visit the website www.glucowatch.com

Some of the articles in the Newsletter are of particular interest to me, where can I find the original complete articles? They can be ordered from your local library, hospital library or from the British Library website www.bl.uk

'Dead In Bed' Syndrome

'Everyone should have the right to choose what sort of insulin they use'

The harsh reality was brought home to us by an e-mail message we received on May 15th 2003:

Dear Jenny,
My husband died after changing to Actrapid Insulin in his late twenties at the age of 29. Up until this time from a child he had used Insulin BP 40 but then he changed to Human Actrapid, lost his warning signs, became tense, agitated and had more frequent occurrences of hypoglycaemia. I think everyone should have the right to choose what sort of Insulin they use. [Name withheld]

IDDT remembers:
Too often we are contacted as families search the internet for information that may offer them an explanation that will help them to come to terms with the death of a loved one. One such person was Tim Seager, whose partner died suddenly before last Christmas. Tim took an active caring role in his partner's diabetes, attending the clinic with her and dealing with her unaware hypos. So when he read of the adverse effects that some people experience with synthetic insulin, he immediately recognised them as the problems his partner had for the two years before her death. He was angry, upset and did a great deal of work on a report for the coroner. He generously gave donations to IDDT because he wanted to raise awareness of the problems so that other people did not have to go through his experience. Sadly the experience was too much for Tim and he took his own life early this year. Tim's mother has now followed in his footsteps and has asked IDDT to continue to ensure that the sudden unexplained death of young people is not ignored.

IDDT offers our sympathies to all the families and friends of the young people who have died in this way and we try to offer help and support to the families under these very distressing circumstances.

We must not forget??.

- Sudden unexplained death in apparently healthy young people with diabetes has become known as 'dead in bed syndrome', an expression first used in 1991 in an editorial published by Prof I W Campbell [ref 1] when he described it as a 'new manifestation of nocturnal hypoglycaemia'. It is usually assumed that the cause is hypoglycaemia but this can only be detected if the post mortem is carried out within 4 to 6 hours of death. The important word from Prof Campbell is 'new'. This is something that many of us can support because prior to this, we were always told 'you can't die in a hypo because your liver will release glycogen, your insulin will run out so that you will come round'. Sadly this can no longer be said.
- There were no records of these deaths being reported prior to

1986 but soon after Professor Toseland, a senior pathologist, raised questions about whether synthetic 'human' insulin was implicated in 19 deaths in the South East.

- In 1991, a study [ref 1] looked at 50 sudden deaths in people with Type 1 diabetes, 22 were dead in bed and 14 out of this 22 had night hypos. All were taking 'human' insulin but strangely the study concluded that human insulin was not implicated.
- A review carried out in 1999 [ref 2] showed that hypoglycaemia is strongly implicated in this type of death and that the death is probably arrythmic. [Arrhythmic means any variation of the normal regular heartbeat.] It points out that dysrhythmias can occur with early autonomic neuropathy in young people which will be compounded by nocturnal hypoglycaemia and this could lead to sudden death in an undisturbed bed.

The British Heart Foundation addresses adult cot death

Adult cot death is a term frequently used to describe an adult version of sudden infant death or cot death where apparently healthy adults die suddenly. A recent study for the British Heart Foundation [BHF] estimates that in England 3,500 apparently healthy adults die suddenly each year and in 150 of these no cause can be found. It is thought that some of the deaths could be caused by inherited electrical abnormalities of the heart that cannot be detected after death. The BHF questions how common these deaths are as this is difficult assess especially if coroners and pathologists around the country are using different words to describe the cause of death.

They believe that if the condition is given an official label, such as sudden adult death syndrome, the deaths could be certified and investigated systematically.

After cot deaths were officially labelled as sudden infant death syndrome, it was possible to collect information, identify possible causes and to make recommendations to protect babies. So the BHF is now funding more research to look for potential causes of unexplained adult death - they are not simply accepting these deaths and doing nothing as appears to be the case with diabetes research! IDDT has written to them to them about the sudden unexplained deaths in young people with diabetes.

No reason for the loss of a loved one

While it is important to remember that these deaths are rare, since we formed in 1994, sadly we are still receiving reports of a number of such deaths. Sudden death of a loved one without a known cause is very hard for bereaved families, something the BHF clearly understand. In all the deaths reported to us, the young people have been using synthetic insulin. Perhaps this is understandable nowadays when 80% of people are using synthetic insulin but this was not the case in the 1980s when the first deaths were reported. More people were using animal insulin and one would have expected some of the people who died to be using animal insulin.

We are told by the regulatory authorities that there are no concerns about the safety of synthetic 'human' insulin??. but it is well recognised that some people using synthetic insulins have reduced or loss of awareness of impending hypoglycaemia. IDDT has always been concerned that it is this loss of warnings that cause severe nocturnal hypos and this could be implicated in the 'dead in bed syndrome'. This continues to be one of IDDT's reasons for trying to ensure that people with diabetes have a fully informed choice of insulin treatment.

Ref 1 Unexplained deaths in Type 1 patients, Tattersall and Gill. Diab Med 1991;Vol 8

Ref 2 Is undetected autonomic dysfunction responsible for sudden death in Type 1 diabetes? The 'Dead in bed syndrome revisited' Diab Med. Aug 1999 Vol 16, 626-631 Simon Heller

Bits And Pieces

Benefit cuts scrapped for the elderly in hospital

People receiving benefits or pensions from the State who spend more

than 6 weeks in hospital have had their benefits or pensions cut by £28.00 a week to pay for their meals and accommodation while in hospital. This has applied to elderly and disabled people, the most vulnerable groups in our society and yet for everyone else hospital care has been entirely free! In his April 2003 budget, Gordon Brown announced that these benefit cuts will no longer be imposed.

Ambulance trusts have to lift recruitment bans on people with diabetes Guidance issued by the Dept of Health in February 2003 says that the blanket ban on employing people with diabetes using insulin in the ambulance service should no longer exist. This follows the changes in driving licence regulations so that applicants can now be assessed on an individual basis by a specialist occupational physician. Applicants who have good diabetic control, good hypo awareness and have no significant complications may be eligible to work as paramedics. This is subject to continuing medical assessment and there will still be certain ambulance duties that people with insulin treated diabetes will not be allowed to undertake.

Community Health Councils [CHCs] will be abolished on 1st September - they will be replaced with Patient Forums within each NHS and Primary Care Trust. They will oversee independent complaints with national standards being monitored by a Commission for Patient and Public Involvement on Health [CPPIH] that started work on January 1st. The government started to replace CHCs some time ago but in the face of strong opposition this was halted. CHCs are independent bodies and opponents to their disappearance believe that Patient Forums will be under funded and will not be as independent or effective because they are within local health authorities not independent of them as CHCs have been. To make this worse the local authorities are not obliged to set up Scrutiny Committees to ensure accountability. Time will tell?????

The OFT recommends greater competition for pharmacies - in January 2003 an Office of Fair Trading [OFT] report recommended greater competition for pharmacies which according to the Royal Pharmaceutical Society, could leave many small pharmacies struggling to survive. Under current rules, anyone interested in opening a pharmacy and dispensing NHS prescriptions must apply for a contract from their local health authority or board. The OFT report says that the strict rules governing how many pharmacies can serve a single area should be relaxed and that any registered pharmacy with qualified staff should be able to dispense NHS prescriptions. They say that present regulations restrict competition and choice for consumers, impose a regulatory burden and limit the ability of businesses to respond to evolving customer demands. The government is not obliged to accept the recommendations and has 90days to publish its response. If these recommendations are accepted, it will not alter the prices of NHS prescription drugs.

Draft Mental Health Bill is a cause for concern. Ministers argue that there is a need to update mental health legislation after nearly 20 years because the public want tighter rules on treating people with mental disorders. The draft Bill is drawn so the result could be compulsory treatment of people with various disorders.

There are concerns over the new definition of mental disorder because it encompasses any disorder of the mind or brain that results in impairment or disturbance of mental function. So it is wide enough to include people with addiction, learning disabilities, diabetes and epilepsy, all of which have already been mentioned in articles in the press. Hypoglycaemia is an impairment or disturbance of mental function and as many people know to their cost, severe episodes can cause violent or abusive behaviour so any changes in this Bill have to be of concern to us all. Many organisations are already claiming that the draft Bill will infringe on human rights issues and also that people could lose control of the type of treatment they receive.

Diabetologists Raise Questions About the NSF For Diabetes

IDDT raised its concerns about the National Service Framework for Diabetes in our April 2003 Newsletter. Now a letter published in the BMJ [ref1] from officers of the Association of British Clinical Diabetologists [ABCD] raises three important questions about the implementation of the NSF - the target-setting plan for diabetes care and treatment for the future.

While the diabetologists welcome many of the NSF proposals, they say that many of them are vague, 'with little indication of how they can be implemented'. Their concerns are:

- lack of resources both that funding is not ringfenced for diabetes and the lack of diabetes expertise in many GP practices bearing in mind that the emphasis of the NSF is that care and treatment will be carried out in primary care ie GP practices.
- The necessary skills in primary care can only be developed with an education programme. The ABCD has already shown that there are not enough consultants, specialist nurses, dietitians or chiropodists in diabetes centres so they cannot see how such an education programme can be provided. There are already major recruitment problems with many hospital trusts not being able to attract diabetologists.
- Without adequate diabetes specialist services, there is a real risk of 'substandard diabetes care in many districts'.

The letter concludes that the funding and staffing consequences of the NSF need to be addressed urgently otherwise the NSF will have little effect and care will not improve.

Once more these bald facts make us wonder if this long awaited NSF for diabetes was paying lip service to the need. It is hard to see how government and those involved in the planning of the NSF ever thought it could happen without specific funding for its implementation, without enough trained staff and without additional training or the resources to carry it out. It seems like making plans for winning the lottery when you don't have the money to even buy the ticket. Time will tell???

Ref 1 BMJ 2003;326:881 [19 April 2003]

23 April 2003 - Government announce cash injection for digital retinal cameras
Ministers announced that they are allocating £27 million to be spent on retinal cameras in England so that every primary care trust will be able to provide eye screening for people with diabetes over the next three years. Hopefully primary care trusts will then be able to fund the training and staff costs to man the screening units.

Restriction On The Number Of Blood Glucose Test Strips

In April 2003 IDDT reported receiving complaints that GPs are restricting the number of blood glucose test strips they are prescribing with one GP practice refusing to prescribe them for anyone with Type 2 diabetes not using insulin. The GP practice stated that they do not alter treatment on the basis of variations of daily blood sugars but on the results of annual HbA1c tests because research shows that testing does not improve overall diabetes control and that the majority of people do no nothing as a result of the test results. Cynical question but what research and carried out by whom?

Since then we have received other similar reports but also where even people using insulin are expected to only use one strip a day! The glib question has to be, if the reason is the same, why have people been doing all these blood tests for so many years, or not doing them and feeling guilty?

IDDT pointed out in the Newsletter, perhaps people don't know

what to do with the results and the answer is that people need better education!

A study published in Diabetes Care, November 2002, showed that people with Type 2 diabetes not taking insulin improved their HbA1c results after testing their blood glucose levels. The research carried out in Austria and Germany compared two groups of people, where one group kept a diary of their results and eating habits and received counselling on diet and self testing and monitored their blood sugars before and after meals at least two days a week. The second [control] group was given counselling on diet and lifestyle only. The results showed:

- the first group reduced their HbA1cs by an average of 1% compared with an average reduction of 0.54% in the control group.
- there was a marked improvement in general wellbeing and significant improvements in depression in the group that tested.

Spot the difference! The group that with the better HbA1cs were taught how to test, how to understand what the results meant AND they were given help with their diet with the opportunity to ask questions about aspects they were unsure about.

Do people with Type 2 diabetes in this country receive this sort of help? In the vast majority of cases, we know that the answer is a big no they don't! Only the day before writing this article, IDDT had a call from a 49 year old man diagnosed with Type 2 diabetes in September 2002 and his mother was diagnosed some months earlier - both on tablets. They are both on the 'waiting list' to see a dietitian but in the meantime, he freely admits that neither of them really have a clue what they are supposed to be doing with their diet. They're testing with some enthusiasm. Do they know how to interpret the results and what to do as a result of them? No and they are they worried and concerned because they want to look after their future health to avoid complications.

No doubt that there are many people with Type 1 diabetes who feel unsure about how to deal with the results of blood tests and are equally confused by the healthy eating diet and they would also benefit from 'counselling' in these areas. Stopping or reducing the number of test strips is not the answer - better education is.

Long memories - home blood testing came in, we weren't 'allowed' to use a glucose meter UNLESS we had been taught how to use it and the healthcare professional was satisfied that we understood this and how to interpret the results. One meter manufacturer even came into hospitals to teach patients how to use their meter. How times have changed!

Stopping or reducing the number of strips shows a failure to understand diabetes and life for people with diabetes.

- It assumes that everyone is the same but people are different, diabetes is different so the need to test will vary in different people and at different times in the same people, such as illness or stress.
- It fails to recognise that people with Type 2 diabetes can alter their treatment as a result of their home tests - if high by they can take exercise or reduce their carbohydrate intake. It also fails to recognise that many people with Type 1 diabetes test before meals, especially those using 4 or more injections a day.
- It conflicts with the constant reminders of the need to test before driving, even short journeys. For some people, this could mean starting a new journey four times a day, so this is 4 strips a day! Something of a contradiction when as an article in 'Practical Diabetes', Sept 2002 says: *'National legislation may soon include blood glucose testing before driving to avoid hypoglycaemia when driving."*
- It fails to recognise that self-monitoring enables people to have more confidence because they know what their blood sugars are doing.

It must be cost cutting!
There is no other logical explanation so is this an edict from Primary Care Trusts [groups of GPs covering a town]? As the reports to us

increase, it is likely to be coming from PCTs. It seems a remarkable coincidence that the National Service Framework for Diabetes has been published but the government has not allocated any extra ring-fenced cash for PCTs to implement its required standards of care. Therefore implementation has to come out of existing funds and you don't have to be a genius to realise that this means cuts somewhere. Is restricting blood testing strips a way of funding the NSF? If so, this is illogical nonsense because if someone has an unaware hypo, 999 is called and there is just one overnight stay, then this would probably cost around £400 but a years supply of strips for testing 4 times a day only costs £423.98!

Some sympathy with GPs and Primary Care Trusts

The position with strips is a reflection of the overall problems that GPs and PCTs are facing with their budgets. The Audit Commission issued a report in March 2003 saying that the high cost of just a few modern drugs is placing enormous pressure on GP budgets that could divert funds away from other vital treatments. However, health ministers insist these latest drugs can actually end up saving the NHS money as patients require less additional help. Statins to lower cholesterol levels and modern blood pressure pills are some of the most widely prescribed drugs nowadays but they are far more expensive than the previous older treatments.

The government says that these new drugs have to be prescribed and PCTs must find the cash to pay for them without any specific extra funding. Although overall funding for GP practices has risen above the level of inflation in recent years, so have the demands upon them.

The figures:

- The overall cost of drugs prescribed by GPs rose by 29% between 1998/99 and 2001/02 to the highest ever, £5.5billion, and this far outstripped the increase in funds made available during that period.
- The Audit Commission predict a further 12% rise in the cost of drugs in 2002/03 which could leave PCTs with a shortfall of £110million.
- The Audit Commission says that its 'prescribing savings database' could help GPs spot what it describes as 'wasteful prescribing'. The BBC report:
- David Lammy, Health Minister, says that the Audit Commission's conclusions do not reflect the overall financial position of PCTs [well, he would, wouldn't he] and how PCTs spend their budget is up to each individual PCT.
- Dr Liam Fox, Shadow Health Secretary, said that PCTs face a big funding gap next year with the average PCT having to make cuts of £360,000 because the increase in their budgets is less than the increase in the cost of drugs.
- The Royal College of Physicians said that all PCTs should review their performance and that new drugs can have a tremendous impact on peoples' lives, provided they are given to the right patients.

These are key words ***'provided they are given to the right patients'.*** Surely this must apply to the prescribing of blood glucose test strips? If people do not test or do not need to test as frequently as others, then prescribing them is a waste of money but across the board decisions without looking at individual needs, is patently wrong.

The full circle!

Many years ago I was the Chairman of the Voluntary Groups Section of Diabetes UK, then the BDA and as such I lead the campaign for blood glucose test strips to be available on NHS prescription. Until then only people that could afford the retail price of £25.00 a bottle could home blood test and in some areas, it seems we are going back to that disgraceful position.

Action

IDDT has written to Mr Lammy to express our concerns. He needs to be aware that government policy is adversely affecting people with diabetes and that the NSF for diabetes will not work if decisions like this are the result. At the time of writing we have not received his reply but we will keep you posted. In the meantime, if you are denied the test strips you need, we would strongly recommend that you first take this up with your GP and if necessary with your local Primary Care Trust. Could you also let IDDT know by contacting Jenny Hirst, IDDT,

PO Box 294, Northampton NN1 4XS, Tel 01604 622837 or e-mail jenny@iddtinternational.org

Why Am I Being Given Metformin As Well As Insulin?

This is a question that IDDT is being asked by people with Type 1 and Type 2 diabetes who are also taking insulin. Many people are aware that metformin is one of the tablets that has been prescribed for Type 2 diabetes for over 40 years, but only in recent years has it been prescribed with insulin for both types of diabetes.

What do we know about metformin?

- It does not cause hypoglycaemia.
- There is a lower incidence of weight gain with metformin than other tablets.
- Metformin does have side effects initially and these can persist in some people. The main side effects are gastro-intestinal, upset stomach and diarrhoea.
- It should not be used in people with renal impairment, not even mild impairment, because it can cause lactic acidosis.
- It should also not be used in other situations where there is a risk of lactic acidosis such as severe dehydration, shock, heart failure or recent myocardial infarction.

[From the British National Formulary]

What does metformin do?
It improves blood glucose control by enhancing insulin sensitivity in the liver, so increases the liver's basal glucose production. It also enhances insulin sensitivity in muscle which leads to an increase in glucose uptake. So in Type 2 diabetes, metformin improves sensitivity and glycaemic control which leads to a reduction in the daily insulin the body needs to produce and this has been demonstrated by research and its use over 40 years.

Not much research into using metformin and insulin in Type 1 diabetes
The situation in Type 1 diabetes is different as there has only been a few studies carried out to look at the effects of adding metformin to insulin treatment and these studies have only involved small numbers of patients or have been uncontolled studies of short duration [ref 1]. This is not exactly robust research on which to base the prescribing of metformin to people with Type 1 diabetes.

Recent research [ref 1]
This study used metformin on people using insulin pumps. It involved 62 people, so it was still not a large study but it was a randomised, double blind study using a placebo [dummy pill] and metformin. This means that neither the participants nor the researchers knew whether people were taking metformin or the placebo.

The results showed:

- After 6 months the people treated with metformin had a reduced daily insulin requirement.
- HbA1c results were the same in both groups after 6 months.
- There were a total of 19 severe hypos in the metformin treated group compared with 8 in those on the placebo. The total of 27 severe hypos was experienced by 8 of the 62 people in the study - 5 on the placebo and 3 on metformin.
- Cholesterol levels reduced during some periods of the study in the metformin treated group but at the end of the study cholesterol levels were the same in both the metformin and the placebo groups.
- Adverse effects [abdominal pain and diarrhoea occurred in 3 people in the metformin group and they dropped out of the study and moderate and mild gastrointestinal adverse effects occurred in a further 8 people in the metformin group ie 11 out of the 31 people taking metformin.

The researchers concluded that the addition of metformin to insulin treatment for Type 1 diabetes was successful in only 23% of patients and that the success of the treatment depended on the absence of adverse effects. Hopefully this is information that will help you if you are faced with the option of trying metformin with your insulin regime.

Ref 1 Diab Care, Vol 25, 12 December 2002, 2153

Joint And Muscle Problems Associated With Diabetes

Joint and skeletal disorders, known as connective tissue disorders, have been recognised as complications of diabetes for some time but they tend to receive less attention than the other complications and the progress of these conditions is often not monitored. This could be because they are not life-threatening but they can be distressing and painful conditions that may alter the lifestyles for many people. One thing that seems abundantly clear, is that no one seems to know the causes of these conditions or if there are certain people who are more susceptible to them. It seems unacceptable to simply put them down to 'long-term diabetes'.

In the IDDT Newsletter April 2003, Rae Price described how she had developed pains in her hands and feet was diagnosed with chiroarthropathy but no one seemed to have heard of it! But she changed to animal insulin and not only felt better but the general stiffness and pain had disappeared. Rae's diary resulted in many phone calls and letters from people with various joint and muscle problems, so we decided to take a look!

Connective tissue disorders
Connective tissue is the material between the cells of the body that gives tissues form and strength. It also is involved in delivering nutrients to the cells around the body. It is made up of a dozens of proteins including collagens. These proteins vary in quantity to provide different structures with varying functions: bone, cartilage, tendons and ligaments as well as fatty and elastic tissues.

Many connective tissue disorders are caused by mutations [alterations] in genes for building tissues and these mutations may change the structure and development of skin, bones, joints, heart, blood vessels, lungs, eyes and ears. Some connective tissue disorders are not directly linked to these mutations but some people may be genetically predisposed to becoming affected. Inherited connective tissue disorders may not be evident at birth but may appear after a certain age or after exposure to a particular environmental stress.

Tests that your doctor may carry out
In connective tissue disorders there may be inflammation/infection present and/or there may be damage to muscles. There are two tests that the doctor may carry out:

ESR Test [erythrocyte sedimentation rate] - this is the 'standard' blood test that GPs often carry out for many conditions to find out if there is any infection present in the body. A high result means that there is an infection and this can then be treated.

Creatine Kinase Test - this is carried out to diagnose and monitor the progress of neuromuscular disorders. Creatine kinase [CK] is a protein found mainly in muscle and it is an enzyme that encourages a biochemical reaction to occur to provide a quick source of energy for the cells. If muscle is damaged, then during the muscle regeneration muscle cells break open and their contents go into the bloodstream. This means that the amount of CK in the blood will rise indicating that muscle damage has occurred and this can caused by chronic disease or by acute muscle injury.

The Disorders

Myopathy
Myopathy is a general term used to describe any disease of muscles,

such as the muscular dystrophies and myopathies associated with thyroid disease. It can be caused by endocrine disorders, including diabetes, metabolic disorders, infection or inflammation of the muscle, certain drugs and mutations in genes. In diabetes myopathy is thought to be caused by neuropathy, a complication of diabetes. General symptoms of myopathies include muscle weakness of limbs sometimes occurring during exercise although in some cases the symptoms diminish as exercise increases. Depending on the type of myopathy, one muscle group may be more affected than others.

Treatment - this varies according to the type of myopathy but may include drug therapy such as immuno-suppressants, physiotherapy, bracing or surgery.

Chiroarthropathy [diabetic prayer]
This is often called limited joint mobility and in people with diabetes generally involves the small joints of the hands, although it can affect larger joints such as wrist, shoulder, knees, hips. It is usually painless but numbness and pain may be present if there is also neuropathy or angiopathy of the hand. Most people do not report the problem until there is some deformity or loss of movement of the fingers. The affected fingers are swollen with a thick, tight and waxy skin and there is an inability to press both hands together hence the term, diabetic prayer. Other disorders of the hand, such as carpel tunnel syndrome and Dupuytren's contracture, have different and distinct clinical features. Chiroarthropathy is linked with more serious microvascular complications of diabetes eg retinopathy, nephropathy and neuropathy, so diagnosis is important. The causes of chiroarthropathy are not really understood.

Treatment - because of the relationship with the microvascular complications of diabetes, improved diabetic control is advised but there is no well established treatment. Physiotherapy is important to maintain movement and prevent further deterioration. Surgery and corticosteriod injections may help in severe cases.

Prevalence:

- 4-14% of the nondiabetic population
- 8.4- 55% of people with Type 1 diabetes
- 4.2 -77% of people with Type 2 diabetes

Studies show a wide variation which could be due to genetic or racial factors or incorrect diagnosis. However, it does increase with the duration of diabetes

Frozen Shoulder [adhesive capsulitis]
An early sign of frozen shoulder is when lifting the arm above the head, reaching across the body or behind the back is difficult. This is followed by pain, often worse at night, the pain then reduces but the range of movement is more limited which may last for 4-12months. In the final stage the condition begins to resolve although surgery may be needed to restore movement. The cause is unknown but thought to involve an underlying inflammatory problem. The capsule around the shoulder joint thickens and contracts leaving less space for the upper arm bone to move around. It can also occur after long periods of immobilisation eg after injury or surgery.

Treatment - drugs such as aspirin or ibuprofen to reduce the inflammation and pain, muscle relaxants, physiotherapy, exercises, heat or ice therapies, corticosteroid injections but surgery only if there is no improvement after several months. Frozen shoulder affects more women than men, usually starts between ages 40 and 65 and affects 10-20% of people with diabetes.

Trigger finger
This is a common condition which results in a bent finger, as if pulling a trigger on a gun. The finger may be swollen, stiff and painful and there may be a bump over the joint in the palm of the hand. It involves the tendons and pulleys in the hand that bend the finger. The tendons connect the muscles to the forearm with the bones of the finger and each tendon is covered by a sheath. As the fingers are bent, the tendons glide backwards and forwards guided by a restraining pulley.

If the tendon sheath becomes inflamed it swells and may develop a nodule or thickening of the tendon. The nodule passes through the pulley as the finger bends but gets stuck as the finger straightens which causes further irritation and swelling until eventually the finger locks in this bent position. The exact cause is unknown. It affects people over 40 and people with a history of diabetes or rheumatoid arthritis are particularly at risk of developing it.

Treatment - aims to reduce the swelling and cycle of irritation so initially treatment is rest, splintering of the finger and taking aspirin or ibuprofen to reduce the swelling and pain. If the problem persists a steroid injection in the tendon sheath can relieve the pain and locking for several months. People with diabetes may require surgery to release the tendon and this can restore movement immediately.

Dupuytren's Contracture

This is a fairly common condition in the palm of the hand that can cause the fingers to contract. It occurs when the connective tissue under the skin in the palm of the hand begins to thicken and shorten and as the tissue tightens it may pull the fingers down towards the palm of the hand. The first sign is a nodule near the base of the little finger and the ring finger. Gradually other nodules may appear across the first joint of the fingers, the skin puckers and the finger is pulled towards the palm. It usually affects the ring finger first followed by the little, the long and the index fingers but there is evidence that in diabetes, different fingers are affected. The problem is not pain but the restriction of movement. Although again the cause is unknown, there is a genetic link because it affects people of northern European decent. It is seven times more common in men than women and usually does not show up until after 40 years of age. People with diabetes, alcoholics and those taking anticonvulsant drugs have a higher risk of Dupuytren's contracture.

Treatment - the only treatment is surgery but this is usually only if the contracture has developed into a deformity. The outcome is usually good.

Carpel Tunnel Syndrome

The carpel tunnel is a narrow, rigid passage of ligament and bones at the base of the hand that contains the median nerve [runs from the forearm to the hand] and tendons. If there is thickening of irritated tendons or other swelling the tunnel narrows and the median nerve is compressed. The symptoms often start gradually at night during sleep with burning, tingling or itching in the palm of the hand and fingers, especially the thumb and first two fingers and this can progress to daytime pain, weakness or numbness in the hand and wrist that may extend up the arm.

It is thought to be a combination of factors that put pressure on the nerve and tendons, rather than a problem with the median nerve itself. The most likely cause is congenital with some people just having a narrower tunnel but other common factors are injury to the wrist that cause swelling, overactivity of the pituitary gland, rheumatoid arthritis, and fluid retention.

Carpel tunnel problems affect three times as many women as men. People with diabetes or other metabolic disorders that can directly affect nerves are more susceptible to compression have a higher risk of developing carpel tunnel problems.

Treatment - obviously underlying causes such as diabetes or arthritis should be looked at first but treatment generally is resting the affected hand for two weeks, avoidance of anything that may worsen the symptoms and if necessary applying a splint to immobilise the wrist. In more severe cases drugs physiotherapy and/or surgery may be needed.

Stiff Man's Syndrome [SMS] now also known as Stiff Person's Syndrome

This is a rare slow progressive neurological disorder and the symptoms are painful contractions and spasms of voluntary muscles, particularly those of the back and upper legs. It is caused by rogue antibodies in the blood causing muscles to lock unexpectedly leaving the person with this condition paralysed for minutes or hours at a time.

The symptoms may worsen when the person is exposed to anxiety or sudden motion or noise. Sleep usually suppresses the frequency of the contractions.

Researchers think that stiff person syndrome may be an autoimmune disorder. How rare is rare? This is difficult to estimate because doctors often think that the symptoms are psychological or due to depression. 50% of people with SMS also have Type 1 diabetes although the link between the two conditions has not been proved scientifically.

It is interesting to note that the information on the National Institute of Health website says that other autoimmune diseases such as diabetes may occur more frequently in people with Stiff Man's Syndrome. Interesting because if we look at the diabetes literature it is described the other way around as a 'rare complication of diabetes'!

Treatment - the drug diazepam, a muscle relaxant, provides improvement in most cases, as do some other drugs. Physiotherapy may also be helpful in some people.

Diffuse idiopathic skeletal hyperostosis [DISH]
This is where there is calcification of the spinal ligaments and the most common part to be affected is the thoracic [chest] spine. It may also be accompanied by general calcification of other ligaments and tendons. The symptoms are stiffness of the neck and back with decreased movement but pain is not the most marked symptom. The cause is not known but the prevalence of DISH is higher in people diabetes than the general population, especially in people with Type 2 diabetes who are obese.

Treatment - there is no evidence that good diabetic control delays the **onset** or improves the condition. Treatment is physiotherapy, aspirin or ibuprofen

If you have experiences with these conditions that could help others, please contact Jenny Hirst, IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail jenny@iddtinternational.org

Rae Price's Diary

In Rae's diary [April 2003 Newsletter] she told us about her experiences from 1998 when she first started to have painful hands, retinopathy. She had various changes of insulin until eventually she decided that animal insulin suited her better. She also discovered she had 'insulin dumping' where somehow her body stores up the insulin and then dumps it into the blood stream at 3.00am and 3.00pm.

Members have written to express their gratitude to Rae for sharing her experiences. Here is part of just one letter we received:

"Thank you Rae for mentioning the 'insulin dumping'. Whilst on genetically modified medication similar to insulin. I used to have severe problems in that I would inject for approximately seven days and then about three days later, I had to cut my insulin to the lowest possible levels. I told my consultant: 'It's as if my body is saving some of the insulin up each day and then uses it about a week later so I keep going hypo.' My consultant called me stupid. This was for the second time, the first time being when he changed me to GM 'insulin', called it human and I asked if it was from human beings - not unreasonable because none of us had it explained to us, did we? Imagine how I felt a few months ago to find that rDNA is used! I hope other people can learn from the horrors I have had to go through. [Name supplied]

Now read more of Rae's diary??.

February 2003
After talking, once again, to my consultant about gaining decent control again he suggests that my GP applies to PCT for pump. Not so many overnight hypos but still occasionally wake up on the floor. Applied to Dogs for the Disabled to see if I can get a dog that can recognise me going hypo, not sure if this is too much to ask but felt it was worth a try.

April 2003
Visited Newcastle General to see about an islet transplant but it

seems my kidneys don't work well enough as I have a trace of protein coming through. The auto immune suppressants also can play havoc with the kidneys so if they aren't working perfectly forget it. We also discussed pancreas transplant but it looks like my kidneys work too well for that as they only do them as a dual transplant. What an utterly depressing day. They also took some pictures of my retinas again and it seems the right eye is due for another laser bashing, yuk!

Two days later my local eye infirmary rang and asked me to come down immediately so that put me into a complete panic. I have been expecting them to tell me for a while now that I can no longer drive due to bad eyesight but the closer it comes the more dread I start to feel. It's going to be like having my legs cut off as I can't go far under my own power. I had another eye examination and all he said was 'your disks are fine and that means there isn't so much of a panic. You will hear from someone else in the next month to arrange for the laser treatment.' Well at least it's not that urgent.

Monday 28 April
Another full day visit to Newcastle General this time for isotopes to be pushed into my bloodstream and them checking how quickly my kidneys get rid of it. Of course all the usual jokes about starting to glow and turning into a green monster were thrown about, but the doctor was very good at hitting the minute vein in my hand to put it in and then 2 hours later hitting the only decent vein I have in my other wrist. The following 4 hours weren't much fun but at least they put a venflon in and shot me full of heparin every time they took blood. I swear they must've taken 3 pints!! Doing my blood glucose testing and injections were fun the next day because I bled everywhere, good stuff this heparin!

And next??..
In May they are going to put a glucose monitor subcutaneously for 3 days then change it and put it in again for another 3 days. I must admit I thought it would be better if it had beeped when I'm low but it seems it's not that sort so we still have to wait for a pump. But at least they are doing something and at last someone is covering every base. It seems they are going to check it all including Addison's and Coeliac disease and an ECG for autonomic nervous system damage?oh well these things are sent to try us.

London Marathon For IDDT

For the first time two people ran the London Marathon to raise funds for IDDT. Scott Freeman and Chris O'Malley both completed the marathon and raise £2000. They don't have diabetes but know someone who has! They know the importance of IDDT's work to ensure that animal insulins remain available for people that need them. Our thanks go to Scott and Chris.

This newsletter is also available on tape or in large print.
If you would like it in this form, please contact Beverley Freeman, tel 01604 622837 e-mail bev@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS

From Our Own correspondents

Thanks to your website
Sir,

What a relief it was to read IDDT web pages relating to 'human' insulin. I have suffered from most of the symptoms described on numerous occasions since I began injecting Humalog 25 15 months ago. I will be in contact with my GP and consultant later today. Many thanks.

Received by e-mail
Name withheld

A variety of issues
Dear Jenny,

I have corneal dystrophy and I have just had my corneas cleaned to enable me to see much better. I understand that some patients are not told that this can be done and are fobbed off by being told that you will have to wait for a transplant. If any of your readers have a similar problem, then it is worth asking about this.

I was surprised to see that some people are being refused blood testing strips and I believe that everyone with diabetes should have this choice. I have Type 1 diabetes and test 6 times a day and increasing the number of tests I do has reduced my HbA1c - my doctor agrees totally with this. I do not believe that everyone should be aiming for 4-7mmols/l before meals because my experience is that levels under 6 give rise to more hypos, which is not going to help anyone and can lead to loss of warnings of hypos.

Finally, it seems that all the time we are hearing at least 5 helpings of fruit and veg a day but I have gastroparesis and filling up on loads of fruit is a great mistake! I am surprised that so little attention is paid to this aspect of diet when so many people with diabetes have gastroparesis. Gastroparesis can cause diarrhoea and so loads of fruit simply makes this worse.

Thank you for all the time you take producing what is always a very interesting Newsletter.

Mr D.D
Lincs

Lantus - for and against!
For?.
Dear Jenny,

Referring to the letter about Lantus from Mr T.D. Worcs in the April Newsletter. Well I have been on Lantus now for 6 months and I find it brilliant with no more severe night hypos, in fact no night hypos at all since my change.

I am also using the mhi- 500, needle free injection delivery system during the day with NovoRapid before meals. I am able to inject in my tummy, arms, thighs and bottom. Mr T.D. said he could not inject in his buttocks with a 3ml pen so perhaps he would like to think about this device instead of using a syringe.

The mhi-500 is so good for me as I have had diabetes for 42 years since I was 12 years old and my injection sites have got quite bad with lipodystrophy and I could no longer inject into my legs and arms as there is no tissue left. Now I can put mu needle-free device almost anywhere. Cheers for Lantus and for the MH 1 500 for giving me hope.

Mrs J.K.
W Yorks

Jenny's comment: It is worth noting that Mrs J.K is now using different injection sites where there is no lipodystrophy [lumps and bumps at injection sites] and this will aid the absorption of the insulin and could be part of the reason for the reduction in night hypos. Whatever the reason or reasons, it is great that she has achieved better control!

The needle free injection device is made by The Medical House and is now approved for use on an NHS prescription

And another!
Dear Jenny,

I was particularly interested to read about Lantus insulin in the April Newsletter. I thought you might like to know that I am using it with Hypurin Porcine Neutral. I have had diabetes for 51 years and I had enormous problems with 'human' insulin. 12 years ago I was changed to animal insulins and I have been using Hypurin Porcine Neutral and Pork Insulatard. Since my retirement from work it has

become increasingly difficult to maintain good glycaemic control, as your correspondent Mr T.D. suggested, due to the very varied levels of physical activity encountered day to day. My HbA1c had increased alarmingly and yet I was having frequent and unexplained hypos quite often at night. My consultant suggested that I try Lantus. I knew that this was a GM insulin but the idea of its beautifully level profile appealed to me and I agreed to try it.

I know that Lantus is not suitable for everyone but I have been using it for 4 months and I have not been disappointed. I inject it before breakfast with Porcine Neutral and inject this Neutral before my evening meal. Prior to Lantus the timing of my evening meal was crucial. Now it is much more flexible. An HbA1c after only two months showed a considerable improvement and I expect this to be bettered in a few weeks time. I have reduced my Porcine Neutral by 25%, night hypos are a rarity and hypo awareness which after more than half a century with diabetes is not ideal, has certainly not deteriorated. It is important to have the correct dosage. Initially mine was too high resulting in some alarming hypos mid morning. It is now .3 units per kg of body weight, as your correspondent, and this seems ideal. I also find that if for example I oversleep, which is very rarely, it is important to reduce the dose accordingly. If these precautions are carried out there is no 'carry over'. It does just as it says - lasts 24 hours. The advertising slogan for Lantus insulin is 'know where you are'. As far as I am concerned it achieves just that.

I would just add that I too have tried injecting Lantus in the buttocks with the 3ml pen. It requires the muscles of a weight lifter and the dexterity of an Olympic gymnast! In other words it is impossible. However, it is possible to inject anywhere with my Owen Mumford Autopen because only light pressure is require for delivery. What we need is a better designed pen for Lantus.

Mr P.C.
South West

Note from Jenny - interesting that Mr P.C. uses pork insulin with Lantus as I have not seen any trials published using this combination of insulins. It is usually used with other synthetic insulins such as Humalog or NovoRapid.

Against??..
Dear Jenny

I wrote to you back in January asking if any of your members had experience of using Lantus as my husbands consultant was keen for him to try it which he agreed to with some misgivings but was assured that he would be closely monitored. This turned out to be a phone call to the Diabetic Nurse once a week for the first 3 or 4 weeks then you're on your own.

Our opinion is that this stuff is dangerous. Not only is my husband not seeing any of the promised benefits but on 3 occasions he did a blood test before bed he had results below 2 (1.3 1.5 and 1.8). All this with NO warning signs despite the consultant promising that he would have better warnings and this was the reason for changing him to Lantus. The Diabetic Nurse just keeps saying 'reduce the dose' and to persevere till he sees the consultant again some weeks away. I would like to warn other members this insulin can cause more problems than it cures!

Mrs T.D
South East

And another!
Dear Jenny,

When I was diagnosed many years ago I was put on Human Actrapid but I had no warnings of hypos, so I was changed to beef insulin and have been fine ever since. A few weeks ago my consultant put me on Lantus and within 10 days I had headaches, joint pains, loss of appetite, huge mood changes and I was very tried all the time. My consultant changed me back to my beef insulin and I have been fine again. I would like to tel your readers of my experience as it shows

that Lantus certainly does not suit everyone.

Mr J L
South

GM or GE
Dear Jenny,

I have noticed that the Newsletters are using the term genetically modified [GM] and genetically engineered [GE] as well as synthetic when applied to human insulins. Is there a reason for this change and could you explain the difference?

Ms S.E
London

Jenny's response: You are correct in that there has been a deliberate change in our policy and we use both terms GE and GM interchangeably and this is a deliberate policy on our part. The first synthetic insulins were said to be 'genetically engineered' and the term genetic modification came in later for the public and was associated with GM crops etc. Nevertheless, both mean much the same thing as there is a 'modification' or 'engineering' of a structure and in the case of insulin, this is either the e-coli bacterium or yeast. In technical literature, synthetic insulins are described as '?being produced either by enzyme modification of porcine insulin or made biosynthetically by recombinant DNA technology or by the modification of a precursor formed by yeast cells using recombinant DNA technology.' So the term GM is probably the most appropriate as the word 'engineered' is not used at all in the technical definitions.

We have found that as a result of the wide publicity associated with GM crops and food, people seem to understand the term GM better than GE and so we are using both terms. For similar reasons we also describe insulins as synthetic and natural because this also enables people to understand the difference in terms that may be more familiar to them.

Booking Of Outpatient Appointments Is To Change

A recommendation by the National Patient Access Team is that partial booking of outpatient appointments is to be introduced and this will include all diabetic outpatient clinics whether with the doctor, nurse or any other member of the diabetes team. [In some areas it may already be in place]

What is partial booking?
It means that if a patient is to have a follow up or a new appointment for more than 6 weeks ahead then the patient is not given an actual date or time when they leave the clinic or when the referral letter is received. Instead the patient will receive a letter nearer the time the appointment is due and this will ask them to contact the clinic to arrange date and time to attend from the appointments that are then available. If the patient does not respond to this letter within 4 weeks then he/she is discharged to their GP for their care. One assumes that special arrangements will be put in place for people who are elderly, deaf or have visual impairment. Although perhaps this is an assumption we shouldn't make - we recently received a report from one of our visually impaired members who received her letter from the clinic with an appointment date but she couldn't read it!

As part of this procedure, the clinic staff have to make commitments to give at least 6 weeks notice of holidays etc. They also have to provide a plan for how their clinics will work, such as how many patients are to be seen and the length of time for each type of patient eg new or follow up.

What is the thinking behind these changes?
The logic is that It should help clinics to run more smoothly by reducing the number of patients who fail to turn up and reducing cancelled clinics. The booking of a set number of patients should give more time to talk to the doctor or health professional. Huge clinics with long waits should no longer happen.

Will this work for diabetic clinics?
As diabetes clinics always seem to be full, even overbooked, and the number of people with diabetes is increasing all the time, the 6week appointments will always be full. In addition, it is hard to see that seeing a set number of patients in clinics will not result in a longer wait for everyone. We already see that in some areas, the 'annual MOT' has become the 18month MOT!

There could also be additional problems because people forget to make the appointment. This could be classed as their own fault but when things are going well, it is easy to forget. It could also mean that teenagers have an easy way out if they actually don't want to attend clinics and many don't simply because they are teenagers and many rebel against their diabetes. This cannot be good especially as their GP may well think that they are still attending the clinic and therefore simply continue to issue repeat prescriptions. This system could mean a greater number of people appearing at A&E or appearing with complications that could have been avoided with regular follow up. The system could be more user friendly, only time will tell but let us hope that it does not result in an increase in complications because of longer times between appointments or lack of follow up of more vulnerable people who fail to respond to the system.

It actually also means that you can't go on holiday or away on business for longer than 4 weeks - if the letter arrives while you are away, you will find that you have been discharged from the hospital to your GP!

Study Shows A Greater Than 50% Increase In Sevre Hypoglycaemia Over A 14 Years Period!

This Swedish study [ref1] involved surveys of 178 people with Type 1 diabetes at the authors' clinic in 1984 and then again in 1998. There was a greater than 50% increase in severe hypoglycaemia. Severe hypoglycaemia was defined as hypos that required the help of others and hypoglycaemia unawareness as blood glucose levels of less than 3mmols/l without the ability to detect warning symptoms.

The authors report that during this period there was an increase in the use of multiple daily injections, self monitoring of blood glucose levels and by 1998, 27% were treated with insulin analogues. However, it is very noticeable that they fail to report that during this period the vast majority of people were switched from natural animal insulin to synthetic GM insulins - forgotten or ignored?

Previous studies have suggested that risk factors responsible for severe hypoglycaemia are hypoglycaemia unawareness, long duration of diabetes, low HbA1cs, intensive therapy [tight control], increasing age and kidney damage. This study included taking the medical history from patients' notes to include all these factors.

Statistical analysis of the results showed:

- ONLY hypoglycaemia unawareness and low HbA1cs were related to the increase in severe hypoglycaemia.
- In patients who had reported severe hypos in 1984 but did not in 1998, the average HbA1c level had increased by 0.2% but in patients who reported severe hypos in 1998 but not in 1984, the HbA1c level had decreased by 0.7%.
- Age and duration of diabetes were NOT significantly related to the increase.
- There were too few people with kidney damage to be able to assess any connection.

While the results were derived from patient self-reporting which means that there could be bias, the authors referred to other studies that concluded that self reporting by such patients are 'usually correct'. Additionally, hypoglycaemia is more likely to be under-reported [especially if there are no warnings].

Authors' conclusion:
'In spite of more frequent use of multiple injection therapy and

more frequent self monitoring of blood glucose, the prevalence of severe hypoglycaemia increased by greater than 50% over 14 years.'

History can't be re-written - only ignored!
Needless to say IDDT just had to respond to this article and has sent a letter to the editor of the publishing journal.

It is to re-write history if it is forgotten or ignored that during the years from 1984 to 1998 the vast majority of people in developed countries were changed from natural animal insulin to synthetic 'human' insulin. It is re-writing history to forget all the people self-reporting increased severe hypoglycaemia and loss of warnings. Forgetting or ignoring patients' reports that a change to animal insulin improves hypo warnings and reduces severe hypoglycaemia is not only re-writing history but may fail to give some people the insulin treatment that suits them best.

Ironically, it seems OK for this study to rely on patient self-reporting and even support its reliability as being 'usually correct' and not dismiss it as 'mere anecdotal evidence. But when patients self report adverse reactions to synthetic insulins and improvements in unawareness following a change to natural animal insulins, why is this not equally accepted as 'usually correct'?

So-called 'anecdotal' evidence from patients should never be undervalued. It is vital for people who don't live with diabetes to remember that severe hypos and loss of warnings are the greatest day to day fears of people with diabetes and their families. It must also be remembered that this over 50% increase in severe hypos reflects an equal increase of these fears and concerns in the day to day lives of all of us living with diabetes.

Ref 1 Bragd J. Diabetic Medicine 2003;20:216-219
Ref 2 Richter B, Neises G. Cochrane www.update-software.com

IDDT Is Not Alone In Concerns About Drug company Funding Of Charities

In IDDT Newsletter, Jan 2003, an article suggested that charities that accept pharmaceutical industry funding should not only declare the full extent of this in their Annual Accounts but should also declare it as a conflict of interest. Researchers involved in drug trials have to do this, as do MPs, so why not charities?

IDDT is not alone in our concerns!
'Which?' the magazine of the Consumer Association [CA] published an article in their April 2003 edition about just this topic, also making the point that patient organisations are trusted by thousands of people but when they accept funds from big pharmaceutical companies, this inevitably raises questions about their independence. Quote CA: *'It's possible that pharmaceutical funding could influence the information an organisation provides. Meaning that patients could be misled or poorly informed.'* They gave examples to show some of the complications that arise:

- **Diabetes UK** - CA highlighted the human/animal insulin situation and the approach of Diabetes UK that receives funding from insulin manufacturers and the approach of IDDT that does not accept any industry funding. Diabetes UK insisted that it has represented the views of those who have experienced problems with human insulin, maintaining that its funding policy prevents donors from exerting any influence. Jenny Hirst, said that IDDT formed because it was felt that Diabetes UK wasn't publishing reports of adverse effects of taking human insulin, although IDDT can't say that the organisation's position was influenced by its relationships with insulin manufacturers.
- **Impotence Association** - has campaigned for the wider prescribing of Viagra and receives funding from the manufacturer Pfizer and Pfizer's logo appears on their website.
- **National Eczema Society** - limits corporate membership to companies that make products related to eczema and 14 of its 16

corporate members are drugs manufacturers.

- **Arthritis Care** - campaigned for the wider prescribing of a new arthritis drug [details in IDDT Newsletter Jan 2003] and their campaign was funded by the drug manufacturers, Pharmacia and Pfizer.

The BMJ published an article by Jeanne Lenzer [BMJ 2003;326:680 29March] about a lay men's group, Us Too! International, which campaigns for men to take the prostate specific antigen screening test for prostate cancer. They claim to be totally independent but receive 95% of their funding from the pharmaceutical industry. They even led an attack on two doctors who wrote articles [one article was published in the BMJ [2002;324:431], saying that routine screening for prostate cancer was not supported by the evidence. This article again raised the question of who do you trust. IDDT made a response to this article that was printed in the BMJ 2003;326:1211 (31 May)

Do we need to know?
Yes, we do! If we, as consumers, know that a charity is receiving funding from the manufacturers of drugs we need for our condition, then we are aware that their information or advice may be biased so we can seek information from more independent sources. We must not forget that omission of information can create bias the information eg simply omitting any information about animal insulin availability results in bias of the information we receive in favour of synthetic insulins.

Drug companies do not give money out of the goodness of their hearts and it is hard to believe that any charity actually believes this! They do it for PR reasons, to have influence and to increase their sales. They cannot advertise their products directly to patients but they know that patient groups can be a strong lobby and can influence governments and the NHS.

Transparency - perhaps the real question is, why aren't the charities transparent about their industry income and simply declare the full extent of industry donations in their Accounts? Why hide their industry funding? It is this lack of openness that leads people to be suspicious!

Just a note: after writing the original article IDDT received a copy of May 2002 Readers Digest that contained a full page advert for Diabetes UK. At the left hand side was their logo and details and at the right hand side was 'sponsored by Novo Nordisk' with their logo and details. In addition a recent visit to the website of the Canadian Diabetes Association, I noted that it had Eli Lilly's name and logo very obviously there!

Seven Years On From The DCCT

The Diabetes Control and Complications Trial [DCCT] was the landmark study that demonstrated that tight control of blood glucose reduces the risks of long-term complications while at the same time increasing the risks of severe hypoglycaemia threefold. It compared people on tight blood glucose control with people on conventional therapy. The study was criticised for several reasons - the participants were highly selected and not typical of the diabetic population and they received a huge level of support and assistance from doctors and nurses in order to achieve tight control - far greater than most healthcare systems can afford. Yet despite this, the target blood glucose levels that people are now expected to achieve are those of the DCCT but without the huge support that the study participants received.

The DCCT participants have been followed up seven years later and it is interesting that the blood glucose levels of the intensively treated group on tight control and those on conventional therapy have narrowed to a point where there is no difference. However, what is significant is that despite the blood sugars no longer being to the targets of the DCCT, the reduction risks of complications, particularly retinopathy, persisted during the seven years after the study ended. Therefore the authors conclude that intensive blood glucose control

should be started as soon as possible after diagnosis aiming for an HbA1 target of 7%.

Perhaps there are other questions that need to be asked:

- Is it impossible to achieve such 'good' blood sugars without the huge support and encouragement of the health professionals?
- Is it simply that people can't maintain this level self-care indefinitely because it infringes on their lives?
- Is it that the threefold increase in severe hypos is just unbearable for the person with diabetes and/or their families?

JAMA 2002;287:2563-2569

Snippets

- Why some women tend to regularly miscarry has never been properly understood. New research has given a clue having found that miscarrying women have a tendency to insulin resistance where there is an inability to transform glucose into energy. [Fert Steril, 2002; 78]
- Parents of large families may have a higher risk of heart disease according to research published by Bristol University. They analysed two studies of 4,286 women and 4,252 men aged 60 to 79. They found that coronary heart disease was lower for men and women who had two children than parents who had larger families. For women with more than two children, the risk was increased by 30% with each additional child and for men, 12% with each additional child.
- Seven people who have recently received the smallpox vaccination as part of the US government's anti-terrorism vaccination programme have developed heart problems with two women dying. US officials had to halt the vaccinations of anyone with a history of heart disease or with the risk factors for cardiovascular problems. Half a million health workers were supposed to be vaccinated by spring this year but not surprisingly, they have expressed concerns and only 25,000 volunteers have actually been vaccinated.

Holidays - Storing Your Insulin

Just to remind you that FRIO Wallets are designed to keep your insulin cool and safe for 48 hours, even in temperatures of 100 degrees Fahrenheit. The main advantages are that there are no bulky ice packs, you don't have to worry about finding a freezer to get supplies of ice and the wallet is light to carry.

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

The FRIO wallet comes in four sizes:

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

The device has been approved by the British Medical Devices Evaluation Unit. For further information or to order a wallet contact the manufacturers at:

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

3ml cartridges for CP animal insulins

Hypurin porcine and bovine insulins are now available in 3ml cartridges which will gradually replace the 1.5ml cartridge range. These cartridges fit the I and 2 unit 3ml Autopen range of pens - Autopen, Autopen Special Edition and Autopen Junior. The 3ml cartridges are not compatible with Autopen 24. The Hypurin vial range remains the same.

Note: in April Novo Nordisk faxed IDDT to say that there was a temporary supply problem with Pork Mixtard 30 and that supplies were expected to be back to normal from May 12th. They also sent a copy of the information to be sent to healthcare professionals to inform them and to tell them about alternative insulins including CP porcine insulin. We are grateful to Novo Nordisk for keeping us informed so that we were able to reassure members that this was only a temporary problem and pleased to see healthcare professionals were supplied with all the alternatives.

Next Issue!

The news has highlighted the recent study showing that low carb diets promote weight loss more than the low fat approach. It is now thought that pump users should use a carb controlled diet, so shouldn't this also apply to people aiming for near normal blood sugars, whatever method of insulin delivery they are using? The rise in obesity over the last two decades raises questions once again about the dietary recommendations of high carb/low fat, not only for the general population but also for people with diabetes. Were these recommendations ever based on evidence of benefit? IDDT's October Newsletter will take another look at these dietary issues.

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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Name: ——————————————————————————

Address: ——————————————————————————

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From Your Editor – Jenny Hirst

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