Once Again - The High Quality Evidence

Cochrane Review comparing short-acting analogues and regular human insulin - May 2004

In May this year the Cochrane Collaboration published a systematic review of the research comparing short-acting insulin analogues [Humalog and NovoRapid] with regular, short-acting ‘human’ insulin. [ref 1] Cochrane reviews are designed to assess the evidence from clinical trials so avoiding bias and providing high quality evidence to help patients and doctors make informed choices about insulin treatment.

The trials:
Altogether 7933 participants took part in 42 randomised controlled studies. 25 studies were carried out in people with Type 1 diabetes, 5 in people with Type 2 diabetes, 5 with a combination people with Type 1 and Type 2 diabetes and one in women with gestational diabetes.

The evidence from the review:

- There was only a minor benefit of short acting insulin analogues compared to ‘human’ insulin.
- Until long term efficacy and safety data are available we suggest a cautious response to the vigorous promotion of insulin analogues.
- Due to fears of potentially carcinogenic and proliferative effects, most studies to date have excluded patients with advanced diabetic complications.
- For safety purposes, we need a long-term follow-up of large numbers of patients who use short acting insulin analogues.
- Furthermore, we need well designed studies in pregnant women to determine the safety profile for both the mother and the
81% of the studies were sponsored by the analogues insulin manufacturers themselves and sponsors were not declared in the remaining 7 studies.

Other information from the review:

- **Quality** - most studies, 83%, were of poor methodological quality.
- **Long-term effects** - no study was designed to investigate possible long term effects (e.g. mortality, diabetic complications), in particular in patients with diabetes related complications.
- **The severity of diabetes** - this was rarely reported in the studies and in the 17% of studies where pre-existing complications were described in detail eg retinopathy, neuropathy and nephropathy, the outcome on these complications when under drug treatment was only reported in one trial dealing with pregnancy.
- **Hypoglycaemia** - 17 studies had to be excluded, some because there was no information. Analysis did not confirm the often claimed advantage of reduced hypoglycaemia after analogue treatment as there were no statistical differences in overall hypoglycaemia when analogues were compared with regular insulin.
- **Nocturnal hypos** - only 6 studies mentioned night hypos and overall nocturnal hypoglycaemic events were presented in only two studies. One showed a significantly reduced rate with analogue treatment from midnight to 6.00am whereas the other study showed no statistically difference from bedtime to breakfast time.
- **Quality of life** - 11 studies reported on quality of life and analogues showed a significant improvement compared to regular human insulin but this was largely due to convenience, flexibility and continuation of treatment. The reviewers suggest that this is probably due to the difference in injection timings with analogues injected immediately before a meal compared to 30 minutes before for regular human insulin.
- **The mitogenic and carcinogenic potential of insulin analogues** - in terms of these effects, the review says that only very limited information on the long-term safety is currently available.

Human insulin has a weak mitogenic effect. [Mitogenic effect mean cell division with the potential for the development of tumours.] The molecular composition of insulin analogues and/or structure has been modified compared to human insulin and these structural modifications could increase the mitogenic potency possibly resulting in the development of tumours especially with long-term use of insulin analogues. This is thought to be due to the structural similarity to insulin-like-growth-factor-1 [IGF-1] and/or faulty signalling through the insulin receptor. The similarity to IGF-1 could also affect the progression of retinopathy.

The first example of this mitogenic effect was in the AspB10 insulin analogue, developed by Novo Nordisk. Trials were stopped because it was found to induce mammary tumours in rats. Therefore the European Agency for the Evaluation of Medicinal Products [EMEA] states that a thorough assessment of the carcinogenic potential is indicated for all new insulin analogues.

More information can be found by visiting http://www.emea.eu.int/pdfs/human/swp/037201eu.pdf and we will be happy to send copies of this to people without internet access. It is also worth looking at the EMEA approval documents for each analogue insulin on their website www.emea.eu

**IDDT is not being alarmist, although we may be accused of it!**
All this information is already in the public domain and we cannot and should not avoid discussion of these potential effects of insulin analogues - they must form part of our informed choice when considering whether to use them. Indeed, at IDDT’s meeting with the Dept of Health [May 26th 2004] when analogues were discussed as an alternative choice to animal insulins, we pointed out that although analogues have not been compared to animal insulin, there is an 80year long-term safety history of animal insulin without obvious tumour development. This cannot be said for the insulin analogues - we simply don’t know and won’t know for many years to come and even then, this assumes that there is or will be continual monitoring of these effects in people using analogues.
Thanks to the Cochrane Review, informed choice is now yours.

Ref 1 Cochrane database Syst Rev. 2004; 2: CD003287

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**Doing Nothing Is Not An Option**

The increased problems with hypoglycaemia and loss of warnings when using synthetic insulin compared to animal insulin were known before they were licensed in 1982 and from the outset Eli Lilly included warnings of this in their insulin packaging. So it still remains a mystery that when patients reported serious hypoglycaemia problems with synthetic insulin, their doctors did not believe them and did not change them back to their previous animal insulin. This is especially strange as a Symposium on Human Insulin concluded:

"There are no obvious circumstances in which human insulin would appear to be contraindicated. On the other hand, there are no clear indications for switching patients with established diabetes to human insulin, except in the presence of immunologic complications of insulin therapy."

[Skyler, Diabetes Care Nov/Dec 1982]

Twenty years later the Cochrane Review comparing animal and human insulins confirmed Skyler’s findings. Twenty years later, patient experiences have demonstrated that significant numbers of people have a range of adverse effects when using synthetic insulins compared to animal insulins. Twenty years later, there still has been no research to compare mortality and complication rates or quality of life in people using animal and synthetic insulins. Twenty years later we face the possible withdrawal of pork insulin by the major supplier in the UK and no one seems to care about the 30,000 people who need animal insulin to maintain their health.

Simplistic thinking perhaps, but we believed that eventually there would be an acknowledgement that some people cannot tolerate synthetic insulins which would result in the continued availability of animal insulins. We never dreamt that doctors and healthcare professionals would not believe their patients. We were wrong! We thought that eventually the professionals would support us to maintain the choice of animal insulin because they do know that all medications have side effects. One size does not fit all! We thought that they would believe the evidence from the Cochrane Review that synthetic ‘human’ insulin is not superior to animal insulin and realise that there is no logical or scientific reasons for refusing to prescribe animal insulin for their patients. We were wrong!

We never envisaged that such an inhumane situation would be allowed to prevail whereby people would be denied the type of insulin they need. We were wrong - the inhumane attitude has already prevailed in most countries outside the UK.

There are no obvious signs of support from anywhere, so we have been forced to seek help from our elected representatives, MPs and MEPs.

**Meeting the politicians…**

The Trustees’ experience of meeting our elected politicians of all parties was quite different and refreshing. They have all shown great understanding and sympathy and not one has doubted that there are people who are not suited to synthetic insulin. They have all questioned the motives of the manufacturers who intend discontinuing animal insulins but not one has doubted the validity of the Cochrane Review or that our fears for the future availability of animal insulins are genuine. It is disturbing that we receive greater understanding and help from parliamentarians than from many of the very people who treat our diabetes.

Perhaps the explanation is simple - their lack of medical training enables them to independently assess the situation using plain
common sense. They understand that not one medication suits all, all drugs have side effects and that in appealing to them for help, we are driven by the need to protect our future health or that of our family members with no hidden agendas, no conflicts of interest and no financial gain.

But parliamentarians also understand that the pharmaceutical industry has become extremely powerful and that there are real concerns over the independence of research. They are aware that pharmaceutical companies influence prescribing habits and use leaders in the medical profession to shape the views of the rest of the profession to promote new drugs. While this influence is denied, common sense alone tells us that drug companies would not spend the huge amounts they do on promoting drugs if it didn’t work!

Doing nothing is not an option
Receiving acknowledgements of the adverse effects of synthetic insulins in some people by diabetes specialists, healthcare professionals and medical experts in the Dept of Health is a battle that maybe we will never win. But one thing is clear - some people cannot tolerate synthetic insulins and they need to know that animal insulins will remain available for them. Two thirds of the 30,000 people using animal insulins are using those made by Novo Nordisk and now these are under the threat of discontinuation.

We know that governments cannot interfere with the commercial decisions. We know that the responsibilities of pharmaceutical companies are to their shareholders but for people whose health will be affected by this decision, doing nothing is not an option. Simply accepting meaningless drug company promises of availability for ‘the foreseeable future’ is not an option. Accepting one supplier of animal insulins in the UK, is not an option - what happens if there is a production problem at this only remaining supplier?

For caring people, doing nothing is not an option because people’s lives and health will be harmed. Doing nothing and allowing the removal of animal insulin will publicly show that insulin treatment is dictated by the powerful pharmaceutical industry and not by the clinical decisions of the medical profession. Is that what patients or the medical profession want?

Richard Smith, editor of the BMJ, says that not giving patients a choice is a form of abuse and remembering this, we will do whatever we have to do to maintain the choice of animal insulin. [BMJ, 14 Feb. 2004]

Silver Linings

The first in a series of articles by Sue Marshall who has had insulin dependent diabetes since she five years old

Hypos!
No one wants to have diabetes but sometimes I take a look at the plus sides of having diabetes and maybe there are some silver linings! Are there any silver linings to having hypos? Well, they are an excuse to be bad-tempered.

We are all told that people get particularly grumpy when they are having a hypo, it is one of the signs to watch out for. As well as knowing that you are starting to feel a bit shaky, realising that you have got an unbelievably short temper is usually a bit of a giveaway that you are having a low blood sugar.

However, many is the time that I have snapped at somebody, then snuck away to do a blood test just to realise that in fact I have got an exceptionally healthy blood sugar level and I am just in fact bad tempered!

Having said that, one of the real upsides to hypos is that they are a great excuse to eat the stuff that you can’t do otherwise. I suspect many diabetics do as I do, and have secret stores of sweets at home.
and at work ‘just in case’.

In my bag I usually carry a small carton of orange juice, having realised a long time ago that orange juice is probably less fattening than a Mars Bar and other hits of sugar that I used to carry around with me. In my kitchen I have a bowl in a top shelf that I put sweets in so that if I have a hypo I can munch on fruit pastilles or Cadburys éclairs or any other bit of sweetness that I am not normally allowed.

What I don’t like about hypos is the obvious fact that they can make you feel rotten, and after you have had a low blood sugar there is a fairly high chance that you are going to have a shooting high one. There’s an inevitable roller coaster between having a hypo, taking some sugar to get yourself out of the hypo, having a high blood sugar, possibly taking a little bit of extra insulin to counter the high blood sugar, and then having another hypo. That’s a vicious circle and needs to be avoided at all costs, mainly by avoiding having hypos in the first place.

Many years ago I remember reading an article called “Make 4 the Floor”. I would like to amend that and say, “Make it Five and Stay Alive”. I have found making ‘4 the Floor’ to be just way too low. It’s officially a hypo at 3.8, so why go anywhere near 4? Five is an awful lot safer as a guideline.

As well as hypos making you feel rotten, and the up and down effect that they have on your blood sugar level, another thing to hate about hypos is how other people don’t understand them.

Some people get quite close to understanding them, because they live with you. They see them happen to you and see their effect. Yet it is astonishing how sometimes people will say things like, “Oh well, you are not having bad ones.” Comments such as that make you wonder quite what kind of a state they would like to see you in. What do they constitute being ‘bad’?

Truly, every diabetic has to get used to the knowledge that they will, on occasion, have hypos, even when they are very well controlled. It is just part of the condition.

I suppose hypos have made me learn not to overreact to them, to take them in my stride, and generally to avoid them by taking care. We all have to find our own balance in terms of where we are happy, and maybe that’s not between the 4-to-8 blood sugar readings that so many doctors seem to think that we are capable of achieving with the relatively blunt tools that we have to use.

Having diabetes in the 21st century is a far better time to have it than ever before. All the equipment is so much more superior to anything that has ever gone before. And hypos, love ‘em, hate ‘em, you are always going to have them.

Sue Marshall has had insulin dependent diabetes for 30 years and has started a company that designs kitbags and organisers for people with diabetes to use to carry all their tools with them as they go about their normal daily lives. For more information visit www.desang.net or call 01273-748575.

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Olympic Honour For Mary Jenkins!

Mary Jenkins, an IDDT member, has had diabetes for over 30 years and has run 10 London marathons, the New York marathon and many other fundraising runs for charity. She is one of the first people to have an islet transplant and although she can no longer run marathons, she says that it has transformed her life. She has now been honoured by being invited to be one of 120 people to carry the Olympic Torch through London on its way to the Olympic games in Athens on August 13th. Congratulations to Mary!
IDDT Goes To Westminster

Lobbying Update
A huge thanks to all our members who have written to their MPs and MEPs. Your help is greatly appreciated and demonstrates the very real need for animal insulins. Thank you too for sending copies of your correspondence to IDDT so that we can monitor the situation. Most MPs and MEPs have written to the Minister and some have written directly to Novo Nordisk. There appears to be standard responses from Lord Warner, Parliamentary Under Secretary of State for Health and from the MD of Novo Nordisk.

Lord Warner’s response is less than acceptable when he says:

- “Insulin suppliers have given assurances that they will continue to supply for the foreseeable future” - meaningless and offers no reassurance whatsoever. It also conflicts with the letter from the MD of Novo Nordisk as you will see below. So your MP is being told one thing by the Minister while Novo Nordisk is saying another!
- “There is no evidence of a safety problem specific to human insulin” And “No significant differences in metabolic control or hypoglycaemia episodes between various insulin species could be found”. True, but he cherrypicks parts of the Cochrane Review comparing animal and human insulin to adversely affect our case. He fails to tell MPs that the Review also said the majority of the research was methodologically poor and, more importantly, it says that NO research has been carried out into mortality and complication rates or quality of life. This why there is no evidence of a safety problem!

Either Lord Warner is being badly advised or a great deal of spin is being put on the facts, both options are cause for concern.

Novo Nordisk’s response makes the following points:

- “…. a lot of people basically only in the UK do have problems with this conversion [to human insulin], and consequently, I expect there is a problem irrespective of the lack of scientific evidence.” Great - an admittance of the problems some people have with synthetic insulin! But it is simply not true to say that it only happens in the UK - just that people who need animal insulin in the UK have been more vocal and more organised than most other countries!
- “It would be fair if a group of people who had an allergic reaction to human insulin agree to participate in a controlled trial under medical supervision using the new insulin analogues.” Fair to whom? Some have already tried analogues with similar results and is it ethical for people known to have adverse reactions to synthetic insulin to be put on trials of another synthetic insulin?
- “An insulin analogue is in principle following the same concept as the animal insulin in the sense that the insulin molecule is not identical to the human insulin molecule.” This is a bit of spin! Analogues are not identical to human insulin but they are not the same as natural animal insulin either!
- “We, as a responsible pharmaceutical company, declare that we will never withdraw a product from the UK market without giving at least 18 months notice.” And “We are continuously discussing with all our stakeholders around this subject the pros and cons of a possible withdrawal of animal insulin. And I expect that we will reach a final conclusion before summer this year.”

Action!
It is vital that you ask your MPs and MEPs to respond to these points and so please do continue to write again to your MP and/or MEP, they are your elected representatives and will follow up your needs. Remember, to try to maintain the choice of animal insulins, doing nothing is not an option!

IDDT meets the Diabetes Policy Section of the Dept of Health, 26th May
IDDT made the following points:

- We have never disputed that the majority of people get on with synthetic insulin but our concerns are for the over 30,000 people who cannot use it.
- Being left with CP pharmaceuticals as the only supplier is an unsafe position.
- Our concern that if/when Novo Nordisk withdraw pork insulin, CP has the capacity to increase their production by the required 66% within the time scale especially if there is a sudden surge in demand.
- The evidence from the Cochrane Reviews of human and animal [2002/3] and of human and short-acting analogues, and we emphasised our concerns about the potential carcinogenic risks of analogues and the lack of long-term safety and efficacy data thus making them an unacceptable alternative for people using natural animal insulins that have an 80 year history of safety.
- That the National Institute for Clinical Excellence [NICE] should issue guidelines on the use of insulins, especially taking into account the clinical evidence and the cost effectiveness of all insulins.
- We asked who is responsible for ensuring that people obtain their essential medications [pork insulin] if there is a shortage.

The outcome produced little new information:

- There appeared to be no acceptance of our arguments about poor quality research and lack of research and little movement from the past position of ‘no evidence’ and ‘the majority of people get on with synthetic GM insulin’.
- It seemed to be accepted that Novo Nordisk will withdraw pork insulin and the year 2006 was mentioned and CP would supply pork insulin when Novo Nordisk withdraw supplies.
- It was accepted that animal insulin had an epidemiological record of safety but no such records exist for the analogues but there are no plans to carry out long-term studies into the risks.
- We received no answer to the question of who is responsible for ensuring that people in the UK receive their essential medicines but interestingly, we were advised to look into alternative sources abroad. Surely this is not IDDT’s responsibility although obviously we have been doing this for several years anyway!

The meeting concluded with:

The Policy Unit said they would look into some of the issues we had raised and suggested the following actions for IDDT:

1. Write to the Medical Research Council requesting research into all insulins.
2. Apply to NICE for a review of insulins.
3. Use our website more to advertise our campaign.
4. Provide information to healthcare professionals.
5. Writes to Diabetes UK to enlist their more active support for animal insulin to remain available.

Our feelings at the end of the meeting?

We may not win but no one will ever accuse any of us of not putting our case strongly enough. We have fought for the last 10 years and we must do this even more strongly NOW. Please do continue to raise this issue with your elected politicians. We know that there will be suffering if animal insulins are either removed or in short supply. If or when this happens, the responsibility will rest fairly and squarely with all those who have ignored the needs of over 30,000 people with diabetes.

IDDT 10th Anniversary Conference

‘The Voice for Choice’

Saturday October 9th 2004

Paragon Hotel, 145 Alcester Street, Birmingham B12 0PJ
REMINDER! We hope that you will join us in Birmingham for this rather special conference in what has been a busy year for IDDT.

Topics include an overview of diabetes, hypoglycaemia, insulin regimes, diet, diabetes and coeliac disease, parent and carer issues and an opportunity to have your say. We will also update you on our campaign to maintain animal insulin.

The cost is £20.00 per person and £15.00 for senior citizens or parties of 4 or more. We can supply you with details of overnight accommodation.

All members should now have received the programme and application form but if you would like further copies please do contact us. Forms should be returned to:

Bev Freeman, IDDT, PO Box 294, Northampton NN1 4XS
Tel 01604 622837, fax 01604 622838, e-mail bev@iddtinternational.org

Driving Licence Removal Due To Visual Field Loss

The message - perseverance, do not give up hope!

One of our members with Type 1 diabetes, let’s call him Jack, applied for renewal of his driving licence on December 2nd 2003 and as requested he visited a DVLA designated optometrist for a visual field check. Some years earlier, Jack had laser treatment for retinopathy but this was not progressive and he has been classed as fit to drive for the years since. In early February 2004 he received notification from the DVLA that his licence was being removed apparently because he failed the visual field test and he had to stop driving.

Needless to say, Jack immediately contacted the DVLA and requested a second visual field test with a different optometrist [at his own expense] and was prepared to see a solicitor if necessary to fight the case. On April 16th 2004, Jack received notification from the DVLA that his driving licence was being reinstated but to quote his wife “This was after endless phone calls and staff rude enough to try the patience of a saint.”

So Jack’s message to other members who have to go through this is: “Do not give up hope, perseverance can make a difference”. If this happens to you, do not give up:

• Appeal against the decision
• Ask for a second test
• If an automated perimeter is used for your check and you fail, then ask for a test with a manually operated perimeter.
• A further alternative is to enlist the help of your ophthalmologist who, up to now, has approved your ability to drive and has taken responsibility for this decision.
• If all else fails consult a solicitor.

So just to remind you of the system:
In the past a report from your own ophthalmologist has been sufficient for the DVLA but they are now requesting that you have a field test with a DVLA designated optometrist [optician]. However, if you have seen your own ophthalmologist recently, then his/her report can be sent to the DVLA instead [preferable]. If you do have a test with an optometrist, make sure that it is carried out by the designated optometrist who receives the fees from the DVLA, and NOT some other person in the practice.

Jackie Banks has fought an almost one-woman campaign about this and writes:

Dear Jenny,
Many thanks to you, Bev and IDDT for supporting me in my ongoing
campaigning connected with the implementation of the EU Guidelines concerning visual fields for driving. This started with the removal of my own licence in 1998 and its subsequent return through the courts in 1999.

Nobody condones unsafe or irresponsible driving and sadly, there will be people with diabetes whose retinopathy does prevent safe driving. My help for individuals has therefore been for drivers who, like myself, had laser treatment for retinopathy many years ago [27 years in my case], have confirmed stable, inactive conditions, know themselves to have complete fields of vision for driving purposes and impeccable safe driving records yet have still lost their licences after failing to meet the required visual fields standards on any testing perimeter, even the Goldmann.

The main reason for this is that following laser treatment, you are taught, or learn, to derive your visual fields by scanning with the eyes. However, the perimeters used to test visual fields require the eyes to be centrally fixed and so the results will be totally unrepresentative of what the driver actually sees.

This and the many other issues arising from it have led to a lot of discussion between myself and the Honorary Advisory Panel on Visual Disorders at the DVLA. Although progress has been slow, I am pleased to report that the Panel has agreed to designate an entire meeting to discuss field defects and progressive/non-progressive retinopathy, a date yet to be fixed.

I have been collating facts and figures related to lost licences and I would be very pleased to hear from any IDDT Newsletter readers who may have been adversely affected by the visual field guidelines. I can be contacted on 0128 775041

Notes:

- As an optometrist, Jenny comments: “Perimeters were never designed to be a definitive test on which to base such vital decisions as fitness to drive.”
- Jackie has written a helpful little book, “Seeing Things Clearly”, ISBN No: 0 948706 13 9, price £4.95 plus £1.00 p&p available from Brent Publications, Fleet House, Armstrong Road, South Benfleet, Essx SS7 4FH
- IDDT raised the issue of driving and visual field loss in our January 2003 Newsletter after correspondence with the DVLA and we would be happy to send you copies of this article, just contact IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or e-mail enquiries@iddtinternational.org

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Patients To Directly Report Adverse Reactions

Regular readers may remember that about a year ago, I greeted with delight Lord Hunt’s [then Minister of Health] announcement that patients themselves would be able to report any unexpected side effects from drugs to the Medicines Health and products Regulatory Authority [MHRA]. You may also remember that this turned out not to be so - patients could only report through NHS Direct and a nurse would then decide whether or not to pass this on to the MHRA! Even worse, it turned out to be a pilot scheme but only piloted in one area, Beckenham! And the results? In a whole year only 39 reports were made by NHS Direct - hardly surprising as it wasn’t ever true patient reporting!

I don’t know if I dare say this but Health Minister, Lord Warner, has again announced that patients will be able to report drug side effects [adverse reactions] to the MHRA using the internet or forms available through GP surgeries. I think this time they mean business because an independent review of the Yellow Card Scheme [the system through which reports are made] has made this recommendation and says that patients as well as doctors WILL be able to report adverse reactions directly to the MHRA. However, yet more consultations are taking place with more pilot schemes, so don’t expect it to
Is this a reaction to recent criticisms?

Patient reporting of adverse drug reactions was not part of the original remit of the independent review but Lord Warner asked them to deal with this issue. According to the Guardian, he said: “I thought that patients were pretty important in terms of giving a quick idea in sufficient volumes of whether there was something worrying about a certain product. If you don’t achieve that, you are missing a trick.”

But we have to ask if Lord Warner was influenced by the recent events surrounding the adverse effects of anti-depressant, Seroxat at high doses. Not only were the Yellow Card reports from doctors found to be incomplete, failing to give necessary information about dose, patient history and the outcome of the adverse reaction but the MHRA were not interpreting the data correctly! Added to this, the head of MIND, the mental health charity, publicly stated that the MHRA had known about the adverse effects of high doses of Seroxat for 10 years before taking action. He also criticised the MHRA for listening far too closely to the concerns of the pharmaceutical industry and not nearly enough to people experiencing the side effect from drugs.

But is patient reporting enough?

Obviously anything that strengthens patients’ rights and involvement over the drugs they take has got to be an improvement. But how effective patient reporting will be is dependent on how the MHRA performs. Will it act on the evidence they receive from patients? Will it treat patients’ adverse reaction reports with due respect and with equal importance as those they receive from doctors? Will it be totally unbiased and independent?

The MHRA is also responsible for licensing of drugs, funded by fees from the pharmaceutical industry and that many of the MHRA advisers/experts have declared conflicts of interest because they have received funding of various sorts. So there is a close relationship with the pharmaceutical industry. Indeed, it is questionable whether the monitoring of adverse reactions should be carried out by the same body that approves drugs or by a totally different, totally independent and transparent organisation whose remit is solely the protection of public health.

How different the situation could have been!

Just imagine what would have happened if patient reporting had been around during the past 20 years and when synthetic insulins came into widespread use - no more convincing the doctor [or nurse] that the side effects were real, no more being accused of imagining them and no more blaming for ‘not controlling their diabetes properly’. But above all, the MHRA would have received thousands of adverse reaction reports from patients. Surely they would have been obliged to act on this evidence from patients, or would they? Perhaps the answer lies in how much trust one places on such a body remaining uninfluenced, independent and caring listening to evidence from patients.

Is There An Analogue War Going On?

“Help me, I don’t want to change my insulin.”

This is an increasing plea from people phoning IDDT which has increased with the introduction of Lantus. They want help and information to argue against pressure from doctors and diabetes specialist nurses to change their insulin, whether animal or synthetic GM insulin, to insulin analogues. Some people feel bullied into changing and IDDT’s role is simply to provide information, support and encouragement to exercise their right to choice. All this is surprising when informed choice, shared care and patient empowerment are high on the NHS agenda and form the basis of the National Service Framework for diabetes.

Reports to IDDT:

Existing regimes, insulins or tiny rises in HbA1cs are being criticised by health professionals in an attempt to persuade them to change to
Lantus [glargine]. Extra appointments are made for group sessions or separate individual ones to convert patients to Lantus and sometimes packs of Lantus are handed out by the nurse without patients even seeing a doctor! It seems that people who are perfectly happy on their present regime are being ‘persuaded’ to change to Lantus even when they have ‘good’ HbA1cs!

All this raises many questions:

• How can people be changed without a doctor being involved? Very few nurses are allowed to prescribe and even then, it has to be within an agreed management plan, agreed also with the patient. How can Lantus be handed out when all medicines have to be dispensed by a qualified pharmacist?

• Have the adverse effects being explained? Are patients informed that Lantus has not been tested in people with complications and none of the analogues have been tested in pregnant women?

• What about the ethics of all this? Medications are only supposed to be changed, if there is a known benefit to patients, so if patients are happy and well on their existing insulin, is it ethical to change them? Is it ethical to change people to Lantus, a synthetic insulin, when they have a known history of being unable to tolerate synthetic insulins?

• What about the cost? Lantus is the most expensive insulin on the market, is it known to be sufficiently cost effective for widespread prescribing in a strapped for cash NHS?

• How come there is the professional time to have extra appointments to convert people to a relatively untried insulin, when people can’t get appointments at the diabetes clinic and annual MOTs are being delayed?

The explanation cannot be that this is all part of a trial because none of the people contacting IDDT have signed consent forms. So perhaps the most intriguing questions of all are where did the Lantus packs come from in the first place and who paid for them? Were they free from the manufacturers and if so why?

Is history repeating itself?
In 1982/83, there was a race between Eli Lilly and Novo Nordisk to be the first on the market with their synthetic GM ‘human’ insulins and to capture the largest market share. But by March 1983 Lilly had not geared up production sufficiently, so their marketing-oriented strategy was to send free samples of Humulin to diabetic clinics and teaching facilities across America BEFORE it was available in the market place. They called this a ‘physician experience programme’, when in reality it was a means of capturing the largest market share ahead of Novo.

Why do I bring this up now? Well, there is a similarity!
While Aventis was the first to market a long-acting insulin analogue, Lantus, they knew that Novo Nordisk was also developing a long-acting analogue, Levemir. So one has to wonder if Aventis have used a strategy similar to Lilly to corner the market share ahead of Novo Nordisk? It is hard to find good reasons for the changing so many patients to a more expensive insulin, especially those who don’t want to change.

Novo Nordisk’s long-acting analogue, Levemir, has now received marketing approval in the EU although it has still failed to do so in the US as further studies are required. Novo Nordisk have already started their marketing strategy as patients are already being told that there is another wonderful insulin about to come on the market! While it will be interesting to watch the tussle for market share, people with diabetes will be stuck in the middle.

IDDT recommends:
Use the evidence that is available: take a look at the Cochrane Reviews of comparisons of ‘human’ and animal insulin and short-acting analogues and ‘human’ insulin. Take them to your ‘discussion’ with your doctor or nurse - IDDT will be happy to supply copies of the shortened versions.

Remember: ask all the above questions and remember there are no long-term studies of safety and efficacy of any of the synthetic GM insulins, especially important with analogues.
Remember: trials of new drugs, including insulin analogues, usually take place in selected groups of patients, usually fit relatively young adults with no complications who are not necessarily typical of the wider population likely to use them and unexpected adverse effects are yet to be discovered. An estimated 50% of people with diabetes do have some form of diabetic complication, so if you fit into this category, the new insulin may not have been tested on people like you. If the Patient Information Leaflet [PIL] says ‘no information available’ or a similar expression, then trials in this group of people have not been carried out. ALWAYS read the PIL BEFORE taking any medication and especially a new one.

Remember: none of the analogues have been tested in pregnant women or those planning pregnancy so any risks to the foetus and/or mother are unknown.

Above all remember: do not be ‘persuaded’ or feel bullied into changing your insulin against your will. You are entitled to an informed choice of treatment and this means that you can say ‘no’. Ethical medical and healthcare professionals will respect your right to exercise your choice and they will not allow this to interfere with your future care.

Is There An Emotional Reaction To The Diagnosis Of Diabetes Mellitus?

By Dr/Almoutaz Alkhier Ahmed, King Faisal Hospital, Saudi Arabia

Introduction
It is a fact that diabetes mellitus is one of the chronic diseases which accompanies the patients until death. So, is it easy for any person to know that fact without an emotional reaction? The answer is no.

From the time that the patient knows this fact, a series of emotional reactions start and these reactions can affect the attitude of the patient strongly toward his/her new disease.

Many physicians believe that improvement of the patients’ life is a crucial target for them. But, is it an easy target to be established?

It is important that the diabetic team should learn and train about how to detect and deal with this emotional reaction or the result will be bad for the future for the patients or their physicians. The doctor/patient relationship should be a positive one. The aim of this article is to highlight the different phases of the emotional reaction following diagnosis of diabetes mellitus.

Phases of emotional reaction:
The emotional reaction to the diagnosis of diabetes mellitus usually passes through four phases, in addition to the times when the complications appear. The sequels of the phases will not be the same for every patient. It is different from one to another.

1) The Denial phase:
This is one of the self-defence mechanisms towards the new invader - diagnosis of diabetes is a fact which disturbs the concept of complete health. Denial may be conscious (suppression) or unconscious (repression).

The patients can deny the diagnosis verbally “I do not have diabetes” or behaviourally “It is OK I have diabetes, but for a week I have not slept well, I have severe chest pain, it may be anginal pain” and the patient starts to behave as a cardiac patient to distort the attention of the diabetic team to another serious health problem.

Other patients designate themselves to behaviour aimed to avoid the issue of diabetes. They may forget, refuse to do or disrupt their required treatment plan. Some patients leave their insulin vials in sunny places or open the refrigerators containing their insulin vials frequently for any reasons (hoping to destroy the insulin which represents diabetes mellitus).
Others seem as though they accept the diagnosis, but they avoid feelings about it by behaviours such as being philosophical or overly concerned about the facts of the situation. Doctor-shopping, that is going from doctor to doctor, in the hope of getting better news is one of the denial tactics used by some patients.

Denial occurs not only with the diagnosis, but also if the patient passes major experiences such as devastating diabetic complications.

2) Anger & Depression:
When the fact of diabetes begins to pass through the denial gates, it is only natural to get angry. In this phase the question almost every patient asks is “Why me? Or why did it happen to my wife or my husband?” Or in case of parents, “Why it did happen to my child?”

Anger is not only felt or spoken alone, but it is also acted out.

Anger can be expressed directly towards medical team who gave the diagnosis to the patient “they do not know what they are doing” or “this laboratory is not good, they fabricate their results”.

Other patients express their anger in indirect ways, such as writing complains against their doctors or bad behaviour such as knocking the doors of their doctors loudly or entering the doctor’ offices suddenly without appointments. Such behaviour aims to give a patient a reason to express his/her anger. What is dangerous is that sometimes anger can be directed towards the self - a child found banging his/her head on the wall screaming why me, another child steals a candy and hides it in a secret place. The patient is aiming to punish the body that caused the disease.

As the awareness of the reality of diabetes mellitus sinks in emotionally as well as intellectually, the patient may get depression. Depression is one of the common psychological disorders accompanying diabetes mellitus. It can be expected when a young patient is noticed to be isolated from his surroundings and started to lose his/her interest in life as well as avoidance social activities.

This phase can be a dangerous one; some patients, particularly adolescents and young adults, may start to practice dangerous harmful practices or habits like fast driving, drinking alcohol or drug addiction.

Bouts of danger or depression or even both may occur even after acceptance of the diagnosis. This may occur when a crisis arises or the discipline of diabetes seems overwhelming.

3) Bargaining:
Another self-defence tactic aims to postpone the acceptance of diabetes “If I am a good patient and do what I am supposed to do, then I won’t have to worry about complications”. Other variations are bargaining with the physician “If I do everything the physician tells me to do, may be the physician will let me eat what I want”.

Bargaining can be noticed in the early remission phase of diabetes mellitus (honey moon period) as the remission in this period can be considered as a reward for being good.

This phase can be used purposely by the patient and/or the physician to eradicate some bad habits: “If I quit drinking alcohol, using drugs or reduce my weight, I am being good and my diabetes might disappear”.

It should be noticed that a patient in this phase can easily enter a bout of depression, particularly if an expected reward did not occur. So, it is important that patients are told only solid facts and their questions should be answered factually by their physicians.

4) Acceptance:
This is the last phase of the emotional reaction and it is the golden aim of all physicians.

Not every one thinks that acceptance is such a good idea but acceptance does not mean resignation and it does not mean giving up. Whether you agree or disagree, what is true is that acceptance means a realistic adaptation to the requirements of diabetes and
making the effort to control the disease in the rest of life. The term \textit{Adaptation} rather than \textit{Acceptance} is preferred by many patients and physicians. Acceptance may only be verbal and superficial "I accept this as a part of my life" and can be deep as mature adaptation “I will make every effort to control diabetes”

\textbf{Recognising the phases}

The phases of the emotional reaction do not occur in the same pattern for every patient. It is not a must that the phases follow the previous order of Denial, Anger & Depression, Bargaining and Acceptance. Some patients may skip a phase to enter another phase, others can stay in one phase for many years while others can reach the phase of acceptance quickly (hours or days).

Family members and health professionals should learn about these phases in order to understand what the patient who has diabetes is experiencing.

\textbf{Major events}

Going through the phases is not a one-time journey. The progression tends to be repeated at each major event in one’s life with diabetes. The major events may include:

- Initial diagnosis
- First expression of hypoglycemia and diabetic ketoacidosis
- Pregnancy
- Recurrent infections
- Surgery
- Presence of long term complications
- Disability

With each crisis, the psychological and physical equilibrium reached by the patient may be disturbed by the new major event. This disturbance may reawaken the feelings first aroused by initial diagnosis.

If the patient’s memory of the previous crisis is a troubled one, the patient may have difficulty with new adjustments. On the other hand, if the patient’s memory of the previous crisis is a good one, the patient may have no difficulties with new adjustments.

Good understanding of the emotional reaction to the diagnosis of diabetes is a crucial issue to establish a good and healthy relationship with newly diabetic patients or those experiencing major events.

\textbf{Emotional Reaction of parents to the diagnosis of diabetes mellitus}

At one stage of life parents participate actively in the formation of the attitude of their diabetic child towards their disease. Parents are the sound of their diabetic child. They are passing through the same phases of reaction. Some time the denial and angry phases are so strong that they can delay the treatment to a critical point. Although it is a natural reaction, it should be considered when dealing with a diabetic child; treat the parents as well as the child.

Children usually take their insulin openly. This behaviour depends greatly on the attitudes they learn from their parents. Hence the importance of including parents of diabetic child in the educational programs since the moment of their child’s diagnosis.

\textbf{The Low Versus High Carb Diet Debate Rumbles On...}

\textbf{Dr Linda Stern, Veteran Affairs Medical Center Philadelphia says:}

“I think a low carbohydrate diet is a good choice because much of overeating has to do with consumption of too many carbohydrates.”

\textbf{Dr Walter Willettt, Harvard School of Public Health says:}

“We can no longer dismiss very low carbohydrate diets but they should include healthy sources of protein and fat and incorporate regular exercise.”
Dr Richard Haslam, Chairman of the National Obesity Forum, UK says:
“There is no doubt that if low carbohydrate, high protein diets are followed properly you will lose weight. What’s always been questioned is the long-term efficacy of such diets and in the short-term, with weight loss, there are certain risks in certain patients - like patients with renal failure.”

Professor Julian Peto, of the Institute for Cancer Research joins in the debate.
In March 2004 Professor Peto told the BBC that he believes that the high protein, low carbohydrate diets could be the solution to Britain’s major obesity problem. He believes that it should be tackled early and children, especially, should be targeted. He said “We need to re-think the dietary advice because the current advice clearly isn’t working.”

He explained that the Atkins Diet works because it involves eating lots of meat and other high protein foods which suppress the appetite and people do not eat as much. However, he also added “The levels of salt and fat are anything but healthy but the basis of the diet, which is low carbohydrate and high protein, is ideal for losing weight.”

People with diabetes on low carb diets know full well that it is possible to eat a low carb diet without increasing salt and bad fats. In turn this lowers the daily intake of insulin and reduces the risks of severe hypos as well as reducing weight with its associated risks of heart disease and some forms of cancer.

Research shows all four diets are good for weight loss

The results of a study of four popular diets were presented at the American Heart Association’s Scientific Sessions 2003 and showed that for weight loss all four diets were equally effective. The volunteers had to follow their assigned diet to the best of their ability for 2 months and the results checked at 2 and 12 months. The diets used were:
- The Atkins - low carbohydrate
- Zone - moderate carbohydrate
- Ornish - low fat vegetarian
- Weight Watchers - moderate fat

Results showed that the some diets were not easy to follow with 22% dropping out of all the diets after 2 months but by 12 months nearly half the volunteers had dropped out of the Atkins and Ornish diets. For the people with diabetes who managed to stay on the diets for 12months, the Ornish diet produced the best results.

<table>
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<th>Diet</th>
<th>Drop in insulin levels</th>
<th>Drop in LDL [bad] cholesterol</th>
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<td>20%</td>
<td>17%</td>
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<tr>
<td>Atkins</td>
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<td>Zone</td>
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Simple way to eat out on a low carb diet

Diabetes Interview is a very useful US magazine for people with diabetes and is edited by Scott King who has Type 1 diabetes. Scott has kindly given us permission to reprint a very useful article published in the March 2004 edition of his magazine. For those on, or contemplating, a low or lower carbohydrate diet, this article not only makes interesting reading but also shows just how easy a simple low carbohydrate diet can be. Remember that this is an article from the US and so the spelling and terminology is a little different but the message is the same.

Going Out on a Lower-Carb Diet
By Joy Pape, RN, BSN, CDE, WOCN

Joy Pape is a registered nurse and certified diabetes educator in private practice, EnJoy Life! Health Consulting, LLC. She is also involved with Laugh It Off!, a diabetes and weight management team, in partnership with a professional comedian, whose business is to educate, enlighten and entertain.

It’s easy to eat out when you’re following a lower-carb meal plan: you simply stop, think and open your mouth! Not in order to feed
your face, but to ask for what you want. If you remember these two principles plan your meal around a protein source, and ask for what you need you can make almost any restaurant work for you (except, of course, a bakery or a bagel shop).

Breakfast

• Most restaurants have eggs, and omelets are a great choice. You can have a different kind every day.
• Ask your server to hold the orange juice, toast and potatoes. Instead, choose Canadian bacon or cottage cheese as a side.
• Add a cup of tea or coffee, and you’ve got a great start on the day.

Lunch

• Salads are a popular choice. Don’t simply think about the salad, however be sure to include your protein source. You can try a chef salad, a Cobb salad, or a caesar salad with grilled chicken, salmon or steak, all of which are usually large enough to fill you up.
• Some of the best salad dressings are olive oil and vinegar, ranch, and bleu cheese. Avoid the sweeter, low-fat dressings, which contain more carbohydrates. Order your dressing on the side and dip each forkful of salad.

Dinner

First look at the entrées.

• Pastas are out, but you have lots of other selections.
• Choose a fish, chicken, beef, pork, turkey or tofu entrée, for example, preferably baked, broiled or grilled.
• Add a dinner salad and nonstarchy vegetables, and you have a great meal. If your entrée comes with pasta, rice or potato as a side, ask your server to replace it with extra vegetables. Make sure the vegetables are nonstarchy ones such as asparagus, spinach, broccoli, or green beans.

Once you choose your entrée, you may want to check out the appetizers.
Shrimp cocktail is a favorite.

Drinks

If you want to have an alcoholic beverage, it would be best to select a light beer or a dry red wine. Remember to drink these with your meal rather than on an empty stomach. By doing so, you decrease the risk of low blood glucose if you are on insulin therapy or if you take an oral diabetes medication that causes lows, such as glyburide, glipizide, Amaryl, Prandin or Starlix.

Three Options

When eating out, always remember you can do three things with your meal:

• Eat it and wear it, in other words, eat too much, and increase both your blood glucose and your weight.
• Eat it and burn it, in other words, eat the right amount, have normal after-meal blood glucose levels and avoid gaining weight.
• Eat some and take the rest home in a doggie bag.

I choose the last two. How about you?

Remember that portion sizes and ingredients vary between restaurants. Ask your server about these, and adjust your insulin as needed if you are on insulin therapy. Check your blood glucose one to two hours after your meal to see how well you calculated.

Note: If you are interested in Diabetes Interview, the address is: Diabetes Interview, PO Box 668, Fairfax, CA 94978-9800, USA or you can visit the website at www.diabetesinterview.com
Drug Choice for hypertension - research looking at 22,576 people over 50 years old with hypertension and coronary heart disease showed that they had similar outcomes when treated with beta blockers or calcium antagonists. The researchers caution that “the decision regarding which drug classes to use in specific coronary artery disease patients should be based on additional factors including adverse experiences, history of heart failure, diabetes risk and physicians best judgement.” [JAMA 2003;290:2805-16]

Scientists may have found an explanation for neuropathic pain - severe neuropathic pain affects thousands of people in the UK and the pain is thought to be caused by subtle nerve damage which can be triggered by a variety of physical conditions including diabetes. Neuropathic pain can be extremely painful and scientists have not understood why such a powerful pain message is sent back to the brain. Now researchers in Japan may have found an explanation - they think the answer might lie in microglial cells which can be found in the spinal cord. They behave like little immune cells and appear to congregate at sites where there is damage. When the researchers took activated microglial cells and injected them into the spinal cords of rats and they developed neuropathic pain. The researchers believe that a protein receptor on the surface of the cell may be responsible and in the rats that developed neuropathic pain, high concentrations of this protein were found. The significance of this is that if the same proteins exist in humans, then a drug could be developed to block its effects and reduce the level the pain.

Hi-tech insole - to help with loss of nerve sensation [neuropathy] in the feet scientists in Boston, USA, have developed an insole that massages the foot with imperceptible vibrations to try to increase blood flow and sensation. Further research is needed to find out the long-term benefits for people with diabetic neuropathy.

Retina cells replacement is making progress - a new approach is being developed to replace damaged retina cells, the light sensitive cells at the back of the eye that pass images back to the brain. Up to now this development uses electronic chips that convert light into electrical impulses that are fed to the brain via the optic nerve but it is difficult to make electronic devices for the eye that are biocompatible. The new approach works chemically rather than electronically by light striking the chip and releasing small amounts of neurotransmitter fluid to stimulate retinal nerve cells. The implant is to be made of soft polymer that will conform to the curvature of the back of the eye. A key component will be retinal nerve cells that have been persuaded to grow behind the chip so that they can be stimulated effectively. It is hoped that they will connect the implant to the optic nerve so that signals can be sent to the brain and scientists believe they know how to do this.

From Our Own Correspondents

It's a global problem
Dear Jenny,

Thank you for the information on your website. I have just spent 20 years of hell on this GM insulin ending up on Humalog and Humulin N and when I complained that I had lost my ability to recognise hypos, I was told that it was just one of those things that happens with these insulins. I had numerous really bad night hypos and convulsions which absolutely terrified me and I was virtually scared to go to sleep. My wife had to give me glucagon.

In August 2003 I took in 42 pages of information to my doctor begging him to change me back to a Beef Insulin. This was after begging them since 1987 to do so because of the things that where happening to me. They finally gave me a prescription for Pork Actrapid and Insulatard and I almost immediately started to feel a difference in myself. The extreme tiredness started to go, the violent flare ups of temper have virtually disappeared, and I began starting to enjoy going to the gym...
to workout, admittedly lightly, but when you get to 62 I think you are entitled to this perk in life!

If I just took one unit up or down I would respond violently to that with exceptionally high or low sugars but on porcine I have stabilised pretty good, not perfect, but am taking less insulin with less violent results. My mental and physical state is far better now. It is a miracle! I can honestly say that Human Insulin has destroyed me. If the authorities do away with the animal insulins then they need to have a hard look at themselves and what they are doing and for what reason they are doing this to their patients. They must be very hard people if they are doing it solely for money. They need to look at why Banting and Best developed insulin in the first place. Come on fellas, look at your hearts and your souls if you have any left.

All the best to you and your organisation.

Mr W.B.
New Zealand

Education and information
Dear Jenny,

Thank you for all the information you have sent to me since I was able to contact you through your newspaper notice. My reaction has been a huge sigh of relief to find so much information and freely given.

I have been on insulin for a year after ten years of various tablets, one of the side effects of them being weight gain. When my treatment was changed to insulin I was warned that there would be a further weight gain but was encouraged to use a 60% carbohydrate eating plan. Naturally the predicted weight gain took place and I am delighted to say that since reading your leaflets on the carbohydrate question and weight and diet, I feel truly informed and have already lost most of my weight increase. I am using NovoMix 30, a synthetic analogue but have no problems with that and my control is extremely good and well within the acceptable levels.

When I was first diagnosed 12 years ago, my constant complaint was lack of information and education. Since making contact with you I feel I have at last found the ‘pot of gold’ at the end of a very wobbly rainbow and I am tremendously grateful.

Mrs S.M
Cornwall

IDDT is biased
Dear Jenny,

I have been receiving the IDDT Newsletter for some months and find it quite interesting but I also find the articles are very biased towards animal insulin - human insulin is always getting knocked. I have been on human insulin for about 25 years and have had no problems and I also know quite a lot of insulin dependent diabetics and only found one who is on pork insulin. My consultant has told me that if I want I can go on to animal insulin but why should I? I’m happy so why rock the boat.

Your Newsletter/Trust is called ‘Insulin Dependent Diabetes Trust’ not Animal Insulin Dependent Diabetes Trust, please don’t be so biased and think of the majority of insulin users who are quite happy on human insulin.

Mr T.I.
North East

Jenny’s Comment - I’d be interested in other readers comments but it is worth remembering that IDDT formed for people who experienced adverse effects with ‘human’ insulin. So yes, we are probably biased but doesn’t this also apply to organisations that have not, or do not, mention the needs of over 30,000 people who cannot use synthetic insulin?
A remarkable consistency in adverse reactions - in so many people!
Dear Jenny,

I was very interested to see IDDT’s summary list of adverse reactions from ‘human insulin’ (HI) detailed in its March mail-out. I doubt whether many drugs have been able to achieve such a remarkable consistency in adverse reactions - and in so many people. As other type 1 diabetics, I can say that I have experienced all the reactions listed by the IDDT. What concerns me is the reluctance encountered at the hospital’s diabetic clinic when I mentioned my concern about the loss of concentration and failing memory. The first doctor I saw, the head of the hospital diabetic clinic, laughed it off with the comment that these come with increasing age and ‘it was nothing to worry about’ and I was only in my 40s! On returning home I used the internet to see if anything had been written on this issue and found numerous papers that dealt with loss of concentration and awareness and memory loss arising through (a) diabetes and (b) hypoglycaemias (‘hypos’).

When I next attended the hospital diabetic clinic, I saw another doctor and repeated my concern to him. While there was no admission that these problems could be linked to diabetes and hypos, he referred me to a psychologist who conducted numerous tests which confirmed the comments I had made. I would add that the psychologist seemed surprised at the first doctor’s response as there is abundant evidence for linking impaired cognitive faculties with diabetes and hypos, and he produced a recent journal in which there was a lengthy article on this very subject. In the case of HI, if it produces more hypos, and these are more likely to be severe, then it follows that it will also increase the risk of cognitive impairment.

In my own case, I used animal insulin for some 25 years before being transferred to HI in 1983. I then used this for 8 years until I returned to using animal insulin in 1991. I have found most of the problems which all suddenly developed shortly after being prescribed HI, have continued to a lesser or greater degree. This, to me, demonstrates that the problems produced by HI can continue even after its use is discontinued and the only way to avoid these is not to use it - ever! - in the first place.

In the matter of cognitive function, I have reached the stage of forgetting to lock doors and windows at night and leaving gas taps on (to cite just a few examples). I have also found myself literally ‘waking up’ while walking across a busy road. In addition to this, I regularly forget the names of people. This reveals the overall danger (as well as the embarrassment) that loss of concentration and memory can present. In sum, the problems caused by HI are both very real and very disabling.

The fact that HI is more expensive for the NHS than animal insulin, HI has no obvious benefits, and so many people have had their lives ruined from the reactions associated with HI (and become a financial burden to an already overstretched health service) indicates a complete absence of logic behind its continued use.

Dr David J. Nicholls
Kent

So much for the new breed of insulins!
Dear Jenny,

I changed to Lantus nearly 12 months ago as I was reassured by my specialist that it was not like the human insulins previously marketed that had caused me so many problems in the past and ended my working life at the age of 32.

So I proceeded to take Lantus with NovoRapid. From there the hell began but I wrote it off as me having to get used to the new insulins! Most days I was just out to lunch - sleeping most of the time! Things did improve in time and my specialists goal to achieve HbA1cs of 7 was achieved before Christmas 2003. At my clinic visit in December we decided to drop the NovoRapid and return to Hypurin Bovine Neutral which did eliminate some of the tiredness but that is all.
However, when I received your letter asking members to lobby their MPs to maintain animal insulins, all the things highlighted hit me like a brick. I have been suffering from increasing joint and muscle pains, fairly extreme depression, very irrational behaviour patterns, aggression etc which have cost me my marriage. It is not so easy to see this when you suffer from them, only from the outside can you see what you are doing. This is what your letter did for me, it seriously made me look at myself.

So Good Friday was the last time that I touched any form of human insulin and its thanks to you that I am here, awake with a full mind. I guess it’s going to take some time for the physical and emotional pains to wear off. So much for the new breed of insulins which I was told by my doctor would not have the same side effects!

I have already written to my MP and will be going to see her in person.

Mr D. F.
West Yorkshire

More On Blood Glucose Test Strips Availability

IDDT continues to receive reports about restrictions on the number of blood glucose test strips being prescribed usually for people with Type 2 diabetes - with some being denied them altogether.

As reported previously, we did write to Ms Rosie Winterton MP, the Minister of Health, and she confirmed that they are still available on the NHS. Subsequently, we raised this issue with Mr Tim Loughton MP who asked the following Parliamentary Questions of the Secretary of State for Health:

1. what diagnostic methods are available on the NHS to allow diabetics to monitor their blood sugar levels?

2. whether he intends that the provision of blood glucose test strips will remain available on the NHS in the long term.

Ms Winterton replied:

There are two types of diagnostic methods available on the National Health Service that allow people to self-monitor their blood glucose levels. These are blood glucose testing strips and urine testing strips. Blood glucose testing strips are available on the NHS for the foreseeable future and I am not aware of any plans to remove them from NHS prescriptions.

Ms Winterton is being somewhat badly advised as urine testing strips do NOT measure blood glucose levels, only glucose in the urine - different and not sufficiently accurate to achieve the target blood glucose levels. However, she confirms that blood glucose test strips are available on the NHS and therefore refusal to prescribe them is a local Primary Care Trust [PCT] policy. Answers to Questions in the House of Lords confirm that recommendations to prescribe them are advisory and not mandatory.

Opposing views from the medical profession!
“People with type 2 diabetes should have as many test strips as they like.”

The Eastern Daily Express [13.4.04] describes the variation in the attitudes of [PCTs] throughout their region with some PCTs allowing 2 strips a week and others having no restrictions at all resulting in anger and accusations of postcode prescribing. There is little evidence that regular home blood testing improves overall control but Dr Richard Greenwood, consultant at the Norfolk and Norwich University Hospital, says:

“My view is that people with Type 2 diabetes should be offered as many tests as they would like. A lot of patients feel more comfortable if their blood test is normal. There is a reassuring element with these strips which is very important with a condition like diabetes. This is where evidence based medicine and what patients want is at odds.
I think PCTs are taking the health economics approach and trying to reduce expenditure whereas they should take a more humanitarian approach.”

But in Coventry there is a campaign to reduce testing!
The Warwickshire Evening Telegraph [5.12.03] gives headlines to a new campaign: “Local health bosses are concerned that people are blood glucose testing too often for no good reason and have launched a campaign highlighting “sensible” use.” The demand for glucose test strips has increased in Coventry with the PCT expected to spend £700,000 by the end of 2003 – roughly the cost of insulin.

Local GP, Dr Rodney Swallow says:

“Some patients are testing themselves at home more often than they need to and perhaps it is becoming an automatic thing. We are not saying that people should not test themselves, it definitely has its uses and it is a basic part of monitoring and treatment, if it is done correctly. Some people may be testing four or more times a day, everyday which is unnecessary. Too much testing can be scary, especially for older people who may become more anxious about their condition. Too much testing can lead to a lot of soreness of the fingers.”

So it is all down to costs!
So costs are dictating treatment advice in some areas of the country and this appears to be regardless of whether they are treated with insulin or tablets! The National Service Framework for Diabetes aims to increase patient empowerment and make them more responsible for their own treatment and care, restrictions on strips is not in line with this thinking!

Have PCTs forgotten that people started blood testing on the advice of healthcare professionals and those patients who did not test were classed as non-compliant? Do they actually believe that people blood test for the fun of it? No, they do it for all the reasons Dr Greenwood highlights - the assurance and comfort of knowing what their blood sugars are to deal with them accordingly.

IDDT’s advice still is that if you are denied the glucose test strips that you need, you should take this up first with your GP and if this fails, with the Primary Care Trust - the local health bosses, to quote Coventry!

Just a thought...
In the normal retail world when goods they are sold in huge numbers, the costs come down, look at DVD players! Has the cost of blood testing strips come down with the vastly increasing sales? Perhaps the time has come for the NHS to renegotiate their deal with the manufacturers rather than see patients denied the test strips they need?

Another Government Back-Track!
In IDDT’s last Newsletter we informed you that from April 2004, patients should receive copies of any letters about their care that are sent from the GP to the hospital and vice versa. This pledge was outlined in the NHS Plan saying that letters between doctors about a patient’s care will be ‘copied to the patient as of right’. The Dept of Health has backed away from this now and describes it as merely ‘best practice’, a very different thing altogether!

Wow - What A Chance!
Dave changed from synthetic insulin on March 21st 2004 and here is his record of the changes that followed...

March 24th 2004
Hi Jenny,
Just thought I would drop you a line to let you know that I have
swapped over to porcine insulins. Wow! What a change! I have only been taking it for three days but so different! I have control! I was using Human Actrapid and Human Insulatard with boosts of Humalog or Actrapid to try to reduce my sugar levels. I changed to Porcine Neutral and Isophane and started by cutting down on my normal dose as it seemed a sensible starting point. So my morning mix totalled 32u rather than 44u. Result? A flat profile all day! Considering I walk at least 3 miles each morning to get to work, am busy all day, then walk across the park on my way home I didn’t have any highs but, showing that porcine still works 12 hours after my morning injection my test at 6pm was 2. This is great as normally I don’t have any control. To get readings of 7 all day is brilliant! So much better than being between 1.6 and 32 with no clear reason.

My GP was actually very amenable about it. I told him I wanted to try an experiment and he said, “I’m sure you know your body better than anyone else and that you know exactly what you are doing. If you want to try it then I’m quite happy to prescribe for you.” We then had a discussion about the local diabetic clinic and how they are very anti any move away from human insulins and that it was a total waste of time talking to them. I only wish I had gone to see him and done it before!

I hope this lasts and it doesn’t fade away as I could use this sort of control for the next 20-30 years until I toddle off!

April 18th 2004

Hi Jenny
Thought I should give you an update! My swap over to Porcine was 4 weeks ago now. So far all plus points. It was strange last week to get some sensations from low sugars. I have had no indicators for on coming hypos for over 18 years. Occasionally I might just get a hot flush but that’s it. So I can normally go right down to 1.6 with no warnings at all. Likewise high sugars are pretty much specifically effect free so it will be interesting to see what happens that way over the weeks. So what do I get now? Well three things; I can’t read my computer screen, I can’t speak without tripping up on words, and my lips go all of a tingle! These all occur at anything less than 3.8 so its just right for me! Just how it used to be all those years ago.

Second great plus point is the weight loss. I have lost just on a stone, a whole 14pounds! I was nearly 16 stones before I swapped. It was gradually climbing and I could do nothing to stop it. I feel faster so you might see me in the sub 3 week mile yet!

Third, and something I can’t really comment on too easily is that my wife says my temper has got better! I don’t quite understand this in that my temper tantrums are all directed at inanimate objects, the vacuum cleaner being my pet hate, but apparently it shows up in subtle ways and I am generally better. All I can say is that comes from someone who would know!

Fourth, my need to sleep mid afternoon (my afternoon during a weekday really starts at around 11am) seems to be going. There is still a tendency to want to sleep after a hypo but I am sure this will change. Fighting that need to shut my eyes while at work in a crowded office was always difficult, to say the least!

Fifth, better control, no stupid highs totally out of control for days at a stretch followed by lows so low you have to eat continuously for 2 maybe 3 hours before it starts to rise.

Sixth and finally. Sex! Oops! Perhaps I shouldn’t have used that word! Actually Penile dysfunction! I hate to admit it but I have been going down that route for the last 3 years. I haven’t spoken to my doctor or at my clinic about it as, having been pulled around quite enough by doctors it would have been like self inflicted trouble to have mentioned it. However, I would be really interested if other swappies now on Porcine have noticed any changes in this department. All I can say is things are looking on the up!!!!

I think someone needs to look urgently at the way the inhibitors and preservatives in Actrapid and Insulatard work, how they are held in the body, how they interact with the products of the thyroid (I have
only a partial thyroid) and the mechanism that switches the insulin receptors on and off. I feel that this is the area that is actually the problem. If you look at the way my profile has gone in the past it would point to the additives rather than the Insulin itself. After all, I could be high for 2 maybe 3 days and could inject 60U additional Humalog in that time and have no drop in sugars other than perhaps 2 points and that some 4 hours after injection.

April 27th 2004
When my GP agreed to change me to pork insulin, I had to agree to trial a mixture of Porcine Isophane and Human Actrapid. I have spent 3 days on this combination. The results? Well, 5lbs put back on in those three days speaks volumes I think! I returned to the Porcine Neutral on Friday and was back to my preferred state in less than a day! I have so far lost 17lbs.

Many thanks for all your help.

Italian Police Complete Inquiry Into Drug Company Incentive Scheme

4,713 people - doctors and GlaxoSmithKlein employees, face possible charges
Italian police have completed an investigation into promotional practices at GlaxoSmithKlein [GSK] and have passed the names to the judicial authorities of over 4,713 people alleged to have been involved in various illicit activities during 1999 -2002. The investigation started in February 2003 and looked at reports that GSK sales reps had allegedly given doctors money or gifts in return for prescribing its products.

Of the 300 GSK employees named, 73 are suspected of corruption and criminal association. The most serious allegations involve whether 60 hospital oncologists, including department heads, received money for every patient treated with the GSK drug Hycamtin. About 2,500 GPs have been accused of prescribing GSK drugs in exchange for gifts or cash bribes ranging from free foreign holidays disguised as conferences to cameras, computers and cash payments.

Scrip 26 May 2004

Insulin Updates

When to inject Lantus
Lantus [glargine] is a 24hour long-acting insulin analogue and is injected once a day. Initially the recommendation was it is injected before bed, then later at breakfast time. A study involving 378 people with Type 1 diabetes [ref1] compared Lantus injected before breakfast, before dinner or at bedtime with Humalog as the short-acting insulin. Over 24 weeks, the results in the 3 groups showed:

1. A non-significant, modest reduction of average HbA1cs
2. There were no differences in the total numbers of hypos with warnings or severe hypos. However, night hypos occurred less in the group who injected Lantus at breakfast [59.5%] compared with dinner [71.9%] and bedtime [77.5%]

The authors concluded that Lantus with Humalog is safe and effective no matter when it is injected but there are less hypos if it is injected at breakfast.

Ref 1 Diabetes Care 2003;25:1738- 1744

Lilly discontinue four synthetic insulins in the UK
Members were informed in the March letter from IDDT that Eli Lilly is discontinuing four Humulin insulins in the UK. Lilly has set up a Diabetes Careline to answer questions about these discontinuations -
0800 783 6764. The products being discontinued are as follows:

<table>
<thead>
<tr>
<th>Product</th>
<th>Discontinue Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Humulin M2 cartridges</td>
<td>By the end of April 2004</td>
</tr>
<tr>
<td>Humulin Lente vials</td>
<td>By the end of July 2004</td>
</tr>
<tr>
<td>Humulin Zn vials</td>
<td>By the end of July 2004</td>
</tr>
<tr>
<td>Humulin M5 vials</td>
<td>By the end of July 2004</td>
</tr>
</tbody>
</table>

**Levemir insulin [determir] research**

June 4th Novo Nordisk announced EU marketing approval for Levemir - a new soluble long-acting insulin basal insulin analogue. The FDA in the US has not given it approval and requires more research.

A recently published study [ref1] compared determir with ‘human’ long-acting insulin [NPH]. Three groups were treated for 16 weeks: (i) determir given before breakfast and at bedtime (ii) determir given at a 12 hour interval and (iii) ‘human’ long-acting before breakfast and at bedtime.

The results showed that the risk of minor hypoglycaemia was lower in both determir groups in the last 12 weeks of treatment mainly due to a 53% reduction in night hypoglycaemia. HbA1c results for each determir group were not different from the ‘human’ NPH insulin group although for the pooled determir groups, HbA1cs were lower. The ‘human’ NPH group gained weight but the determir group did not. [Just a note I cannot resist - how long have our members been complaining of increased weight when using ‘human’ insulin???] The researchers conclude that overall glycaemic control was improved compared to long-acting ‘human’ NPH insulin.

Ref 1 Diab Care 27:1081-1087, 2004

**Snippets**

**Apologies again for any post delays**

We can only apologise again for any delays or non-arrivals of post from Northampton. We do our best but the Postal Service in Northampton has been named the worst in the country by Post Watch!

**Hostility raises your blood pressure!**

Researchers in Chicago tested 3308 young adults to find out if impatience, competitiveness, hostility, depression and anxiety had any effects on the development of high blood pressure. They found that hostility dramatically influenced blood pressure, depression had a slight effect but impatience had none at all.

[JAMA, 2003;290:2138-48]

**Love has a strange effect**

Research looking at men and women who had fallen in love during previous 6 months showed that men had lower levels of testosterone than normal and women had higher levels than usual. The researchers suggest that it is as if nature wants to remove the differences between men and women because survival is more important at this stage. Another study has discovered that being in love can affect the neural circuits in the brain that are normally associated with critical social assessment of other people. These are suppressed when people are in love and may account for why ‘love is blind’!

**Having someone to talk to best for low moods.**

A light-hearted survey found that ‘having someone to talk to’ was the top choice to allay the blues but there was a gender difference as only 68% of men chose this compared to 83% of women. More than twice as many men than women chose sex to lighten their mood whereas women preferred spending time with their families! There was also a regional divide with Londoners and people in the Midlands most likely to talk about their blues while people from the North West, Wales and Scotland least likely to want to. People in the North East most frequently chose sex as a coping mechanism.
Lunacy, say the BMA!
From January 5th 2004, the Government introduced fines of £100 a day to local authorities when patients have been kept in hospital needlessly. This usually happens when people are waiting for their local council to find them a place in a care home or for improvements to be made to their own homes to accommodate their needs. This is supposed to give councils an incentive to move faster to prevent bed-blocking. But the Dept of Health is giving councils extra money to pay the fines -£50million! While the Dept of Health say that some of this money is to be spent on improving services, a BMA spokesman described this as lunacy and an ill thought through policy. Sounds about right!
If you would like to join IDDT, or know of someone who would, please fill in the form (block letters) and return it to:

IDDT
PO Box 294
Northampton
NN1 4XS

Name: _____________________________________________
Address: ___________________________________________

_________________________________________________________________
Postcode: ____________________________________________
Tel No: _______________________________________________

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From Your Editor – Jenny Hirst

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