



# Insulin Dependent Diabetes Trust

October 2008 Newsletter



## Justification for IDDT's position on synthetic insulins

- IDDT has always argued that animal insulins must remain available for people who are unable to tolerate synthetic insulins – both human and analogue insulins.
- IDDT has always expressed concerns that the long-term safety of insulin analogues has never been established.
- IDDT has openly criticised Novo Nordisk for their stated intention to discontinue all their other types of insulin and only supply insulins analogues. Apart from reducing insulin treatment choices, this leaves few alternative insulins for people who experience adverse effects with analogues.

## NEW warnings about NovoRapid justify all IDDT's concerns!

### Warnings in the US about NovoRapid

NovoRapid (insulin aspart) and called NovoLog in the US, is a rapid-onset, short-acting insulin analogue produced by GM technology by Novo Nordisk.

**On March 14th 2008** the US Food and Drugs Administration (FDA) approved safety labelling revisions for NovoRapid to warn of the risk of systemic hypersensitivity reactions in patients receiving this and other insulin products.

**On August 13th 2008** the FDA issued further warnings of the risk for severe, life-threatening, generalised allergic reactions in patients using insulin products, including post-marketing cases of anaphylaxis in those treated with NovoRapid. They also warn that generalised

allergy to insulin may cause whole body rash, dyspnea (breathing difficulties), wheezing, hypotension (low blood pressure), tachycardia (rapid heart rate) or diaphoresis (sweating).

**The evidence used by the FDA** to issue these warnings was from controlled trials where allergic reactions were reported. Allergic reactions occurred in 3 of 735 people treated with regular human insulin and 10 of 1394 people treated with NovoRapid. Information from controlled and uncontrolled trials of NovoRapid also revealed 3 out of 2341 people discontinued using NovoRapid due to allergic reactions.

**FDA now advise:** that people using NovoRapid should be advised to obtain immediate medical assistance if a rash develops over their whole body, if they have trouble breathing or if they experience a fast heartbeat or sweating.

#### **Is the UK issuing similar warnings about NovoRapid?**

The Summary of Products Characteristics (SPC) documents for all synthetic GM insulins have always had warned about anaphylactic reactions:

*“Symptoms of generalised hypersensitivity may include generalised skin rash, itching, sweating, gastrointestinal upset, angioneurotic oedema, difficulties in breathing, palpitation and reduction in blood pressure. Generalised hypersensitivity reactions are potentially life threatening.”*

In the SPC for NovoRapid these reactions are classed as ‘very rare’ and by the standard SPC definition, ‘very rare’ means these adverse reactions occur in about 1 in 10,000 people. However, the evidence from controlled trials used by the FDA shows that they occur in 10 of 1394 people treated with NovoRapid which, by standard SPC definitions, shifts these adverse reactions from the category of ‘very rare’ to ‘uncommon’. ‘Uncommon’ adverse reactions affect between 1 in 100 and 1 in 1000 people.

#### **IDDT has asked questions of the UK drug regulatory authority (MHRA)**

- Is the MHRA going to take similar action to the FDA and issue warnings to patients and doctors about the severe allergic reactions to NovoRapid and the risks to people with diabetes? If not, why not?
- Is the list of adverse reactions to NovoRapid going to be revised so that allergic reactions are moved from ‘very rare’ to ‘uncommon’? If not, why not?

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## **Government Report - Still A Long Way To Achieving Good Quality Of Diabetes care**

Many readers will remember that in 2003 the National Service Framework for Diabetes [NSF] set targets for standards of care for people with diabetes which all have to be achieved by 2013. The idea behind the NSF is to ensure that everyone with diabetes should receive the same standard of care, no matter where they live. Local Primary Care Trusts [PCTs] are responsible for making sure that these targets are met.

#### **Five years later, the Government has issued a report on the progress of meeting the NSF targets.**

- Just half of patients are receiving the standard treatment.
- Improvements are being made to reach all 12 NSF targets. The target that everyone with diabetes should receive screening for retinopathy [eye disease] by 2008 has not been achieved in all parts of the country. Progress is being made with the treatment of other complications but there is still a long way to go in terms of prevention.
- There is a need to increase the number of diabetes specialists.
- The report praised the work being done on involving people in their own care.

- More needs to be done to improve the management of medical emergencies, specifically hypoglycaemia.
- The access to specialist care for children with diabetes and pregnant women with diabetes is very variable and needs to be improved.
- The NHS has improved its record of early diagnosis of people who were unaware that they had Type 2 diabetes – over 600,000 have been diagnosed over the last 5 years. However the report adds that there are still a further 500,000 people undiagnosed.

### **Still a long way to go**

No doubt there have been improvements and we know from our members that some areas of the country provide excellent care but what about the rest? There is certainly no room for complacency as we still receive many calls from people who are certainly not receiving the care they should and many people, especially those with Type 2 diabetes, don't seem to have received very much education about their condition, the food they should eat or generally how to manage it.

### **Was setting the NSF targets putting the cart before the horse?**

The report comments on the increasing number of people with diabetes, Type 2 in particular, but this cannot be used as a reason [or excuse] for not meeting the targets as this increase has been predicted for many years.

The principle of setting targets of standards of care to be achieved by Primary Care Trusts has many advantages. However, there was a shortage of specialist staff and education programmes etc prior to setting the NSF targets, so as the NSF also included diagnosing the undiagnosed, can the targets ever be met? Was setting targets without the necessary staff putting the cart before the horse? IDDT raised this question at the time.

### **What's the state of play now with staffing levels?**

From figures published in Clinical Medicine 2008;8,4:377-380

- the number of diabetes consultants has increased but the time they spend on diabetes has fallen from 40% in 2000 to 26% in 2007. 75% of their job plans are spent on non-diabetes related activities.
- 94% of diabetes consultants are spending more time in acute-general medicine which means less time spent for training juniors in diabetes.
- There is less time for developing community services with GPs and only 12.8% of consultants involved in diabetes community clinics.

Another survey carried out by Diabetes UK in 2007 showed:

- only 38% of Primary Care Trusts [PCTs] provided psychological support for adults with diabetes compared with 64% in 2006. For children only 51% provided this care compared with 69% in 2006.
- There is still a shortage of paediatric diabetes specialist nurses and in 41% of PCTs their case load has increased with an improvement in only 7%.

With figures like this, can the NSF targets be met? Greater investment in diabetes care is necessary but this seems unlikely.

So what can you do in the meantime? Don't accept poor care, don't accept delayed or no retinopathy screening, complain to your local Primary Care Trust as they are responsible for funding services in your area.



## **Pork Insulin And Pumps - can You Help Us?**

IDDT receives a number of calls from people interested in using pork insulin in an insulin pump. We are gathering information that currently does not seem available to patients or professionals about this to try

to assist in decision-making.

So we interested in making contact with people who are using pork insulin in pumps, people who would like to use an insulin pump with pork insulin and those who have talked to their health care team about doing so. We would like to know more about their views and experiences and what their diabetes health care team think about this as an option.

We believe that most people using animal insulin in pumps are using pork insulin but if you are using beef insulin, do get in touch as we would love to hear from you too.

If you fit into any of these categories and are prepared to help us by filling in a short questionnaire, please contact Jenny at IDDT on 01604 622837 or e-mail [jenny@iddtinternational.org](mailto:jenny@iddtinternational.org)

We would very much appreciate your help.

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## Introducing Martin

Hi Everyone,

As a newcomer to the staff of IDDT, I was very pleased when Jenny asked me to write this article for the newsletter so that I can introduce myself and tell you a bit about my background. As you know, IDDT prides itself on the fact that most of us involved have a connection in some way to a person with diabetes. I am no exception to that fact – my sister has lived with diabetes for 33 years being diagnosed when she was five and I was six. In my previous career I worked as a registered care home manager for adults with learning disabilities, several of whom had Type I or Type II diabetes and I often found myself going to Jenny for advice about management and care.

My memories of growing up with a sister with diabetes are very mixed, some very happy, others not so happy, but that's just the same as anybody isn't it? I don't really remember the conversation I must have had with Mum and Dad, when I was told that my sister had been diagnosed but I do remember spending what seemed to be hours sitting outside the children's ward at the hospital. I suppose I used to feel a bit jealous of the attention that she was getting but found it difficult to say this because I knew she was ill and that was selfish and then I'd feel guilty. I think I was a bit confused to say the least.

That said there was an upside – all this fascinating new stuff that came into the house, metal and glass syringes with screw on needles, urine testing kits with fizzing tablets, test tubes and colour charts. My sister and I discovered that if you put enough of these tablets in a test tube with some water then they could get so hot that the tube would crack – a bit like Mum's temper when she found out what we had been doing!

Like any brother and sister we also used to argue and sometimes these were because she was hypo and thus bad tempered but what then used to happen was that she would have something to eat and wonder what the fuss was about and why I was still cross. These days I've just realised that she doesn't have to be hypo - sometimes she is just plain bad tempered.

Anyway there are loads of different feelings and emotions and memories that go along with living with someone who has diabetes and they are far too numerous and complex for me to write about them all here but if I can be of help to anyone, then please don't hesitate to get in touch.

Things have certainly changed since my sister was diagnosed. I can remember Mum fundraising for the local branch of then British Diabetic Association and raising enough money to buy the first blood monitor for the children's ward at the general hospital – it was the size of a house brick.



Coming back into the loop, starting to work for IDDT has made me realise how much there is to know and how mind-boggling the choice of treatments can be, so even though I have quite a lot of experience of living with someone with diabetes I can only start to imagine what it is like to be someone who is newly diagnosed or a member of their family.

Martin is employed to help to both raise funds and raise the profile of IDDT but he has the added 'advantage' of having a sister with Type 1 diabetes! Sometimes parents are worried about how their children without diabetes are feeling, so if you would like to talk to Martin, give him a call on 01604 622837 or e-mail martin@iddtinternational.org or write to him at IDDT, PO Box 294, Northampton NN1 4XS

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## IDDT News

### **Thanks to Sue Morris**

Sue has been a Trustee of IDDT from the formation in 1994 and treasurer for many years. Due to pressure at work, Sue has had to resign as a Trustee of IDDT so we would like to thank her for all the work and support she has given to IDDT over the last 14 years.

### **IDDT's Annual Report for 2007**

The Annual Report for 2007 will be approved at our Annual General Meeting on October 11th 2008. To save funds we are not sending the Annual Report to all our members but will give a summary in the January 2009 Newsletter but copies are freely available to anyone who wants one – just contact IDDT on 01604 622837, e-mail enquiries@iddtinternational.org or write to IDDT, PO Box 294, Northampton NN1 4XS.

### **And congratulations are in order!**

#### **To Ruth Rigby who is 14 years old and has Type 1 diabetes**

Ruth contacted IDDT because she wants to help children and young

people with diabetes in developing countries. Ruth put the idea of sponsoring a child with Type 1 diabetes in India to her school year group and they decided to have a 'Mufti-Day' and a cake sale. They raised the excellent sum of £225.84 which will pay for the insulin and medical care for a child at Dream Trust in India for year. Ruth and her year group now have a photo of Aarti and information about her family and schooling so that they can all see how they are helping to take care of her and her diabetes.

IDDT would like to say her huge thank you to Ruth and her year group for helping Aarti whose family is too poor to be able to afford the vital insulin that she needs. A special thank you must go to Ruth for her initiative and for thinking about other children with diabetes.

### **To Jackie Banks for fighting the DVLA**

As we reported in the July 2008 Newsletter, the DVLA has finally accepted that retinopathy is not always progressive and some people are now receiving their driving licences back after several years of being refused a licence. We all have Jackie Banks to thank for this as she has worked tirelessly to achieve this situation. We are pleased to report that the DVLA form sent to people who state that they have had retinopathy treatment now has boxes included to cover this situation. Jackie, whose retinopathy has remained stable for over 25 years, recently received her new form, filled in the boxes and received her driving licence without the usual battle! So we congratulate Jackie and thank her for all her hard work and persistence.

### **Nationwide Community and Heritage Award to Jenny Hirst**

IDDT's Co-Chairman, Jenny was a winner in the Community – Individual category of the East Midlands region. This was for the work she has done for people with diabetes through IDDT. She accepted the Award at a lunch in Nottingham and never known to knock, she handed out IDDT cards to several people with diabetes also attending!

### **To Brenda Smith and The Greene King Summer Charity Darts League**

We must thank Brenda Smith and her family for choosing to hold their Summer Charity Darts League in aid of IDDT. Over £1400 was raised

and a presentation made at the finals at the Tally Ho public house in Lewes. Brenda's friend and IDDT member, Kathryn Millbank received the cheque on behalf of IDDT and made a short speech about diabetes and IDDT. Our thanks go to Brenda, Kathryn and all those who helped to raise this wonderful amount for IDDT and enjoyed themselves at the same time!

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## Warnings About Byetta

Byetta [exenatide] is a relatively new injectable drug for the treatment of Type 2 diabetes.

In the UK acute pancreatitis associated with taking Byetta is not listed as an adverse reaction but the information document [SPC] does say there have been 'rare spontaneously reported events of it and warns that patients should be informed of its symptoms: persistent, severe abdominal pain.'

**In October 2007** the US FDA [the drugs regulatory body] announced that it was investigating 30 reports of acute pancreatitis in people taking Byetta, Since then it has received reports of 6 cases, two of which were fatal.

**In August 2008** the FDA reported that anyone using Byetta who experiences persistent abdominal pain should seek immediate help from their doctor. A few days after this latest announcement Amylin reported a further 4 deaths from pancreatitis and the share price in the company dropped by nearly 25%. The FDA is working with Amylin and Lilly, the manufacturers, to add stronger and more prominent warnings to the labelling of Byetta. Apparently as a defence, the manufacturers pointed out that people with Type 2 diabetes have a 3 times increased risk of pancreatitis than those without diabetes anyway. But this begs the questions of whether or not it is advisable to take a drug that appears to increase this risk even further.

## And while we are on the subject, you should also know...

Avandia and Avandamet – after these Type 2 diabetes drugs were linked with heart failure and death, the debate about their use rumbles on but Australia seems to have made its mind up! Changes have been ordered by the Therapeutic Goods Administration and under new guidelines, no patients with any degree of cardiac failure should take them, they must not be taken with insulin and no new Type 2 patients should be started on triple therapy [3 drugs in combination]. The manufacturer, GSK, says ALL patients using Avandia or Avandamet need to see their doctor as soon as possible.

**Regranex** [becaplermin] – is a prescription gel made by Johnson & Johnson used to treat diabetic leg and foot ulcers caused by neuropathy. A long-term study completed in 2001 found that there were more deaths from all types of cancer in people using Regranex than in those who did not. This prompted a further study which showed that these deaths were higher for people who were given three or more prescriptions for treatment with Regranex.

In the US, the FDA now recommends that Regranex is only used where the benefits can be expected to outweigh the risks. In the UK the SPC does not include the risk of cancer as an adverse reaction but warns that in view of the lack of data, Regranex should be used with caution in patients with known malignancies – not the same thing.

**Champix** [Varenicline] – it has been known for some time that this non-nicotine, anti-smoking drug can have adverse effects. In the US during the last 3 months of 2007, Champix was linked to 988 serious reported injuries – far more than any other drug in this time period. After analysis of all reported adverse events since marketing approval in 2006 the FDA found Champix linked to a wide range of problem Including serious accidents and falls, serious cardiac rhythm disturbances, severe skin reactions, seizures, diabetes, psychosis, aggression and suicide. They have issued a Public Health Advisory about the most marked adverse effects – behavioural changes, agitation and attempted or completed suicides and with the recommendation that caution is exercised about its use and that alternative methods are used to stopping smoking.

## Discrimination Or Just Downright Ignorance?

In our July 2008 Newsletter we discussed discrimination at work and that although we don't generally consider diabetes to be a 'disability', it does come under the Disability Discrimination Act. However, one of our members encountered discrimination on holiday, although it is debatable whether it is discrimination, ignorance or just a total lack of care for fellow human beings! Here is Christine's experience.

*I was booked in to a B&B in Combe Martin for 5 days in August. It took me 6 hours to get there and when I arrived I filled my car up with petrol so that I could travel around Devon, checked into the B&B and paid in advance for my 5 day stay.*

*On the second day, I had lunch, went for a wander on the beach and then went back to the B&B about 2.30pm. I felt a bit tired so laid in bed watching TV. I must have had a hypo because I came round at about 7.30 lying between the two beds surrounded by a paramedic and two ambulance staff. It took a while to come round properly as the paramedic did not give me Glucagon - I cant remember if she said she didn't use them or didn't have one. I declined going to hospital as I felt there was no point – I have had diabetes for 38 years now and have had a few episodes of severe hypoglycaemia like this before and once pumped full of sugar or glucose I am fine. The paramedic stayed until about 9pm and then left.*

*The owners of the B&B were in and out of the room, when the wife said I would have to leave "as they were not running a care home". I was so angry I wanted to leave there and then but had to wait until the next morning.*

*The next morning I woke up and asked if the owner would help me with my boxes of dialysis fluid because they were too heavy for me to carry to the car. They said they could not do this until after breakfast. As I was getting into the car to drive off, the husband said "I was welcome to come back but next time bring a carer". I pointed out I did not have special needs and did not need a carer, and was so annoyed*

*I just drove off. To add to all this, they did not give me any money back!*

*When Christine rang IDDT about this, words failed us! Here is someone maintaining her independence, unfortunate enough to have a hypo while on holiday. It can happen to anyone with Type 1 diabetes but to be treated with such ignorance is unbelievable!*

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## Can You Help IDDT?

### eBay Weekend

Almost all of us who have access to the internet have heard of eBay, the on-line auction site, and quite a few of us have used it to buy and sell items - over 20 million people at the last count!

What a lot of people don't realise is that every time they sell an item on eBay they can raise money for charity – including IDDT.

### How to donate to IDDT by selling stuff on eBay – it's really quite simple

1. Log on to [www.e-bay.co.uk](http://www.e-bay.co.uk)
2. Once you're ready to sell your item, go to the Sell hub and select 'Advanced Sell'. If you're stuck you can get some tips on how to list.
3. As you are filling out the details, look out for the charity box just below where you set your price. Select IDDT and the percentage of your final selling price that you would like to donate [10% - 100%].
4. A week after your item sells, Missionfish [eBay's charity partner] will automatically collect the donation from you. You can also manage your donations through the 'My donations' section of My eBay, under the 'My Account' tab. Any fee credits will appear on your next invoice.

## **Everyone's a Winner!**

**You Win** - every time you list an item for charity, you'll get a fee credit on your basic insertion and final value fees equal to the percentage you donate. So if you donate 50% of your selling price to a charity, eBay will waive 50% of your fees.

**We Win** – every time you sell an item, Missionfish will collect your donation and after deducting a small fee to cover administration, pass your donation on to IDDT.

## **We know it works, thanks to Jean**

Jean from Darlington has been donating to IDDT through eBay in memory of her husband who sadly passed away in April last year. Jean has listed 139 items over the last few weeks with every one raising money for IDDT. Jean has not only shown that donating by selling on eBay really does work but she has also raised much needed funds for IDDT. We are really grateful to her for her kindness and generosity. So a huge thank-you to Jean!

## **IDDT's eBay weekend, January 17th and 18th 2009**

Of course you can start selling items on eBay to donate a percentage to IDDT anytime and we are always grateful for your help. But we are making January 17th and 18th 2009 'IDDT's eBay Weekend' by asking everyone with internet access, to get involved. It's a good opportunity to sell any unwanted items, especially any Christmas presents that maybe you don't really want! If we all list our unwanted items, however small, and donate a percentage to IDDT, not only can we have some fun but we can raise a tidy sum – the old saying of look after the pennies and the pounds take care of themselves.

## **Other ways to use eBay to help IDDT**

### **If you run a business that uses eBay, you can help too!**

If your business uses eBay to sell then you can also register to donate to IDDT, again with benefits:

- your listings are highlighted with a yellow and blue ribbon,

- your business is associated with a good cause and
- there are significant tax benefits.

For more information go to [www.ebay.co.uk/ebayforcharity/sell.html](http://www.ebay.co.uk/ebayforcharity/sell.html) and click on the link to businesses.

## **Special Auctions**

The final way you can help IDDT is by holding a special auction. A special auction is hard to define but they tend to have one or more of the following features:

- 'money can't buy', one of a kind items or experiences,
- items with celebrity status,
- unique or extraordinary items,
- extremely valuable or rare items.

If you need any help or have any ideas or items for a special auction, then please contact Martin at IDDT tel 01604 622837 or e-mail [martin@iddtinternational.org](mailto:martin@iddtinternational.org)

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## **NICE Guidance On Insulin Pump Therapy July 2008**

NICE issues guidance is about the use of medicines, devices and treatment in the NHS in England and Wales. The new final NICE guidance for insulin pump therapy has resulted in changes to the 2003 recommendations. Here are the main points:

1. Pump therapy is recommended as a treatment option for adults and children 12 years and older with Type 1 diabetes provided that:
  - attempts to achieve target HbA1cs levels with multi daily injections [MDIs] result in the person experiencing disabling hypoglycaemia.



[This is defined as repeated and unpredictable hypoglycaemia that results in persistent anxiety about recurrence and is associated with a significant adverse effect on quality of life.]

or

- HbA1cs have remained high [8.5% or above] on MDI despite a high level of care.
  
- 2. Pump therapy is recommended as an option for children younger than 12 years provided that:
  - MDI is considered to be impractical or inappropriate, and
  - Children on insulin pumps would be expected to undergo a trial of MDI between the ages of 12 and 18 years.
  
- 3. Pump therapy should only be started by a trained specialist team who should provide structured education programmes and advice on diet, lifestyle and exercise appropriate for people using pumps.
  
- 4. After adults and children have started pump therapy, it should only be continued if it results in a sustained improvement in glycaemia control [a fall in HbA1cs] or a sustained decrease in the numbers of hypos. Appropriate targets for these improvements should be set by the responsible physician in discussion with the person or their carer.
  
- 5. Pump therapy is not recommended for the treatment of Type 2 diabetes.

More information and the full NICE Guidance for insulin pump therapy is available from: [www.nice.org.uk/TA151](http://www.nice.org.uk/TA151) or phone on 08454 003 7783 or e-mail [publications@nice.org.uk](mailto:publications@nice.org.uk)

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## Intresting Comments On Continuous Glucose Monitoring Systems By A User

We all place high hopes on the development of continuous glucose monitoring systems. These are now available but are only to be used to pick up trends in blood glucose levels and cannot be relied on for making dose adjustments.

There was an interesting letter in Diabetes Health [22 May 2008] from a medical student who has had Type 1 diabetes for over 10 years. He is using a Medtronic insulin pump and continuous glucose monitoring system [Paradigm Real-time]. He warns people not to have unrealistic expectations of the current generation of continuous glucose systems as both the Dexcom and Paradigm Real-Time systems are good to monitor trends in blood sugars but they are inherently limited in several ways. He suggests that perhaps the drawbacks are not emphasised sufficiently by the manufacturers selling these expensive systems. The drawbacks he describes are as follows.

- The readings are delayed in time and can lag behind the actual blood sugar concentration by as much as 20 minutes. This is because they sample interstitial fluid [fluid in the cells] which may take up to 20 minutes to change in the same direction as blood glucose. Standard finger-prick monitors use capillary blood which represents the current blood glucose levels. This time lag means that they cannot reliably protect against hypoglycaemia as 20 minutes can be too long before treating the hypo. This is not helped by the sensors being inaccurate at both high and low blood glucose levels.
- Both manufacturers warn that continuous monitoring systems are

not a substitute for finger-prick testing and decisions about insulin dose must be made on the basis of finger-prick tests. So using continuous monitoring does not reduce the number of daily finger-prick tests. A further drawback is that the continuous monitors must be calibrated multiple times a day.

- These devices and the sensors are very expensive costing between £400 and £500 in the UK and the disposable sensors cost £15 to £20 each. Added to this, the Medtronic system is only lasts for a year until the transmitter ceases to hold a charge and then a new transmitter has to be purchased.
- People using a pump need two subcutaneous insertions and for slim people this can be a problem as the abdomen fat they use for the pump insertion site may not be large enough for two insertion sites. Unlike the pump infusion set, the sensor probe of the continuous monitoring system bends more easily and therefore any area of the body that is continuously being flexed or that bears weight is not a good choice for the sensor probe to be inserted.

Undoubtedly continuous glucose monitoring systems are useful for people who wish to monitor trends in their glucose levels but as this user points out, people need to be aware of the drawbacks too – informed choice again!

### **What does research say?**

Trials have mostly failed to find a significant improvement in control with continuous glucose monitoring [CGM] compared to finger prick tests. Several studies have shown that CGM may help to detect night hypos and one study showed that CGM helped to motivate people with Type 2 diabetes to take more exercise.

A recently published study investigated the safety and clinical effectiveness of a new device with a combined insulin pump and continuous monitoring system compared to a pump with standard finger prick testing. [Diabetes Technology and Therapeutic, Vol 10, No 5 2008] 146 participants between the ages of 12 and 72 were randomised to receive the two different methods of measuring blood glucose levels.

The results showed that HbA1cs reduced in both groups but with no significant difference between the groups. Greater than 60% use of the continuous monitoring system did result in a reduction in HbA1cs. However, the finger prick testing group showed no increase in hypoglycaemia [3 severe hypos] but the continuous monitoring group showed a significant increase [14 severe hypos].

Another report ‘Continuous blood glucose monitoring: does it really affect diabetic control?’ provides information about changes in glycaemia control after a single 72 hour use of CGM. Many people failed to show an improvement in HbA1cs after 4 to 6 months but people who used the CGM system because of hypo unawareness found a high rate of night hypos and they were able to make insulin dose adjustments to avoid this. People with high HbA1cs and inconsistent results with finger prick testing were unlikely to pick up trends or patterns in blood glucose control with CGM.

This supports current evidence suggesting that continuous glucose monitoring cannot be recommended to improve control in every patient but it may be useful in selected people, especially for the investigation of loss of hypo warnings [hypo unawareness]. [Pract Diab Int July/August 2008, Vol 25 No 6]

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## **Lack Of Activity May Not Be To Blamr for Obesity**

We frequently hear that lack of exercise and today’s sedentary lifestyle [along with eating too much] is a major cause of the rising level of obesity. However, recent research carried out at the Universities of Aberdeen and Maastricht has discovered that we burn the same number of calories on physical activities today as we have done over the last 20 years during which time obesity levels have risen hugely. The research found that there has been no reduction in the daily energy we use so this suggests that increased food intake may be the more important influence in obesity.

Surprisingly they also found that there is very little difference in the energy used by people in the US and Europe and people in pre-industrial in developing countries. One comment from Professor John Speakman from Aberdeen University is interesting: "It seems that we have been misled by the anecdotal information about levels of our physical activity. When actual measurements of energy expenditure are analysed there is no evidence for a reduction over time."

It seems that this is yet another case of assumptions being made rather than looking at the actual evidence from research. While it can never be denied that exercise is healthy, this latest research suggests that governments have made recommendations about how to combat obesity and overweight on assumptions not evidence. They have also spent fortunes on getting a message across that appears to be anecdotal!

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## It's Alimentary

### **An historical commentary by Robin Odell and Non Davies**

The BBC television series, *Casualty 1907*, based on The London Hospital in Whitechapel, provided some dramatic and gritty reminders about advances made in medical treatment. 'The London' has a reputation for innovation in the treatment of trauma and disease. Not least in its record of achievements is its role in treating Diabetes Mellitus in the days before insulin revolutionised life for sufferers.

This new frontier in managing the disease was set out in a small book of lectures by

Dr O Leyton, published in 1917. Dr Leyton was Physician to The London Hospital and his lectures to colleagues and medical staff described *The Treatment of Diabetes Mellitus by Alimentary Rest*. The convention up to that time was to put the diabetic patient on a carbohydrate-free diet; the new idea was to allow a period of

alimentary rest leading to changes in metabolism approaching that of a normal individual.

Patients suffering from severe forms of the disease were unable to utilise even the carbohydrate portion of their protein intake. Leyton found that after alimentary rest, patients were able to use the carbohydrate in protein and also to oxidise some starch. Asked if the new treatment would help prolong the lives of young diabetics, he answered emphatically with one word, 'undoubtedly'.

The physician recognised that in the normal healthy individual there was a balance between physical and chemical processes within the body, creating a stable equilibrium. He also understood the part that emotions such as anger, fright or stress could play by increasing the activity of the suprarenal glands, with the result that sugar was liberated into the bloodstream.

The new treatment consisted of starving the patient, sometimes for nine days, until sugar had been absent from the urine for 24 hours. Then the carbohydrate tolerance was established in a diet containing very little protein and practically no fat. After a carefully controlled dietary regime lasting 15 days, the calorific value of the patient's intake was increased and if no sugar was detected in the urine, carbohydrate could be gradually increased accordingly.

The success of this approach was demonstrated in treatment figures for the year 1916. Of 66 cases of severe, often comatose, diabetics admitted to 'The London', 39 were treated with alimentary rest and, of these, 29 were recorded as leaving the hospital sugar-free and on a diet of around 2000 calories.

One of Dr Leyton's patients in 1917 was a 26 year old soldier repatriated from the Western Front. His weight was down to less than nine stones and he was passing urine at the rate of seven pints daily. He had been diagnosed as diabetic by army doctors after being wounded in the trenches. After six weeks in hospital and showing no response to conventional treatment, his case was considered hopeless.

On being transferred to Dr Leyton's care at 'The London', the soldier was given immediate alimentary rest and after nine days his urine was sugar-free. His response fluctuated but by the middle of 1917 he was sugar-free, had gained a little weight and was able to undertake light work.

In a modest preface to his book, Dr Leyton referred to the treatment of diabetic patients 'by a method yielding much better results than those obtained in the past'. By such pioneering efforts is progress achieved. He also graciously acknowledged the help of his fellow physicians at The London Hospital.

*Dr Leyton's lectures were published in The Clinical Journal in 1917 and in book form the following year by Adlard & Son & West Newman Ltd, London.*

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## IDDT Helps In Zimbabwe

One of IDDT's new members is a doctor in Zimbabwe. He was interested in IDDT's Information Pack and the experiences of some of our members who have adverse effects when using synthetic insulins including reduced or total loss of hypo warnings.

But as we hear on the news, the situation in Zimbabwe is very difficult and Dr Keletso Nyathi wrote:

*"We don't have much to say on the subject of choice of insulin, we don't have a choice as patients are happy to find any insulin at all! Having a chronic illness in Zimbabwe is really difficult for most people, especially those with diabetes. There is an erratic supply of medicines and the government is more concerned with supplying HIV medicines.*

*But I do understand your concerns and I agree that patients should*

*be able to choose which insulin to use – animal or 'human'. People with diabetes are the best people to decide what is best for them and no study can replace patient experience. Please keep fighting for the rights of people with diabetes to choose what's best for them. I applaud you!"*

IDDT sent Dr Nyathi 6 unused blood glucose monitors and 600 test strips which had been donated to IDDT by you, our supporters. He is now able to do instant blood glucose tests on his clinic patients. Here are the thanks from Dr Nyathi:

*"The blood glucose meters will go a long way in helping the management of our patients.....Even though we have a sign which says 'Supported by IDDT', we already have raised eyebrows with people asking why I'm doing free blood tests [because these days nothing is for free!] This move has made more people aware of your organisation as people are always asking who IDDT is. Thank you for being a caring organisation."*

### **To our supporters**

This just shows what a help our collection of unused, unwanted, in-date supplies is to people in other countries, so thank you to everyone who sends in unwanted, unused supplies.

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## Adverse Drug Reactions Can Occur With All Drugs

With the new warnings issued in the US about adverse reactions occurring in some people using NovoRapid and the warnings about Byetta being associated with 6 deaths, perhaps we should take another look at adverse drug reactions, what they mean and why they are important to us as patients.

IDDT has always had a keen interest in adverse reactions because

so many people have experienced them when using synthetic GM insulins yet have not been believed by their doctors or healthcare team. As has been said many times before, it is difficult to understand why there is such a resistance to believing that GM insulins can cause adverse reactions as it is well known that all drugs can do this, so why should insulin be any different? Convincing doctors, health professionals and drug companies that some people have adverse reactions to GM insulins has been, and still is, an uphill battle but for people with diabetes who have experienced them, yet when changed to animal insulin are better, there is no doubt that these adverse reactions are real.

### **What is an adverse drug reaction?**

An old article [BMJ 1998;316:1511-1514] defines an adverse reaction as any noxious or unintended reaction to a drug that is administered in standard doses by the proper route for the purpose of prophylaxis [treatment to ward off disease], diagnosis, or treatment. The article also says that some drug reactions may occur in everyone, whereas others occur only in susceptible patients.

### **Certain types of reactions occur only in susceptible people and these are:**

- **Drug intolerance** - a low threshold to the normal pharmacological action of a drug [the way a drug works]
- **Drug idiosyncrasy** - a genetically determined abnormal reaction to a drug related to a metabolic or enzyme deficiency
- **Drug allergy** - the immune system rejects the drug and this reaction reoccurs if the drug continues to be given
- **Pseudoallergic reaction** - appears to be like an allergic reaction but is not caused by the immune system reacting to the drug.

*So as only a percentage of people have adverse reactions to GM insulins, is there a group of people with diabetes who are particularly susceptible to GM insulins?*

### **Risk factors for adverse drug reactions**

Adverse drug reactions occur mainly in young and middle aged adults and are twice as common in women.

- Genetic factors may be important. For instance, the HLA type may predispose adverse reactions to aspirin and insulin allergy. But what does this mean? The HLA consists of genetically determined antigens which are substances that cause the formulation of antibodies. HLA incompatibility causes the immune response or rejection reaction.
- The drugs themselves can also be risk factors and these include macromolecular size ie large molecules, which may be complete antigens eg insulin.
- The method of administration of the drug may also be a risk factor and adverse reactions occur least often with drugs that are taken by mouth and most often with those given intravenously. [What about those given subcutaneously like insulin?]

### **When do adverse drug reactions occur?**

They can occur at any time throughout a drugs life – immediately after taking, within weeks, months or even years after taking a drug. IDDT has always advised people to read the Patient Information Leaflets [PILs] inside the packaging of drugs and this is true for drugs or insulins that you have been taking for some time. Why? The warnings may change as new adverse reactions are found. The clinical trials carried out to gain marketing approval of a new drug are relatively small using selected people so the adverse effects may only show up over time with greater use in the wider population. Insulin is no exception to this advice as the recent new warnings in the US about NovoRapid have shown!

### **We know little about a drug when it first hits the market**

As we have said before, but it is always worth saying again, before a drug is licensed the clinical trials that are carried out are in relatively small numbers of people, could be between 1500 and 2000 people. In addition, these people may be highly selected which means that they are not necessarily typical of the wider population who will be taking the drug. These trials are also funded by the manufacturers of the



new drug and therefore are not exactly independent!

For example, pre-licensing trials for a new insulin may and often do use people with diabetes who are not the very old, not the very young and have no complications, so at the end of the trials all we know is whether the drug is safe in this particular, healthy group of people and what adverse drug reactions they experienced. When that very same new insulin reaches the market, it will be used thousands or millions of people with diabetes many of whom may have quite different health situations from the pre-marketing trial participants. It is estimated that 50% of people with diabetes have some forms of complications – how will they be affected by the new insulin? Some people have had diabetes much longer than others – will the new insulin affect them differently? Some people will be taking other drugs for other medical conditions – will the new insulin affect them differently?

We simply do not know the answers to any of these, and many more questions when a drug or insulin first reaches the market. What we do know is that drug companies issue press releases that sing the praises of their new 'wonder' drug and it is easy to be misled by press reports that rarely mention known or unknown side effects!

### **Understanding the risk of adverse reactions**

In making a choice about whether or not to take a drug or insulin, one of the things that we consider is any possible adverse reactions to a drug or insulin. It is important that we don't get the risks of them occurring out of perspective. For instance, if we are told that an adverse reaction is common, we probably all have different views of what this means. Those who overestimate the meaning of common may be put off using a drug that would be useful to them.

On drug information sheets [SPCs] the definitions are as follows:

- very common:  $>1/10$  which means the adverse reactions affect more than 1 in 10 people.
- common:  $>1/100, <1/10$ , the adverse reactions affect between 1 in 10 and 1 in 100 people

- uncommon:  $>1/1000, <1/100$ , they affect between 1 in 100 and 1 in 1,000 people.
- rare:  $>1/10,000, <1/1,000$ , they occur in more than 1 in 10,000 people but not as many as 1 in 1000
- very rare:  $<1/10,000$ , they affect less than 1 in 10,000 people.

### **How does this relate to insulins?**

The UK SPC for NovoRapid classes the allergic reactions to NovoRapid as 'very rare' but the clinical trial results that prompted the FDA to issue warnings about NovoRapid showed that the allergic reactions occurred in the 'uncommon' category – occurring in between 1 in 100 and 1 in 1000 people.

These same trials showed that the allergic reactions to human insulin occurred in 3 of 735 people also making them 'uncommon'. Interestingly, the SPCs class the allergic reactions to Actrapid, human insulin made by Novo Nordisk, as 'uncommon' but to Humulin R, made by Lilly, as 'very rare'. So presumably adverse reactions can be different with different brands of the same type of insulin.

**Note:** Although adverse reactions to animal insulins have been collected since the 1960s, no warnings of such severe allergic reactions are included in the SPC documents for pork or beef insulins. For Hypurin Porcine Neutral – the SPC 'there is minimal evidence of them occurring at all'.

### **The importance of reporting adverse drug reactions**

After a drug reaches the market studies are carried out to look at the various effects of the new drugs [post-marketing studies] but again, many of these are funded by the manufacturers of the new drug and therefore not independent and the quality of the studies may not be good. For example, readers may remember that one of the comments made in the Cochrane Reviews of various synthetic insulins was that the studies were 'methodologically poor'. This means that we are making our treatment choices on the basis of poor quality research – not good!

One of the major ways that the safety and efficacy of drugs are monitored is through the system of reporting adverse reactions – in the UK it is called the Yellow Card Scheme. This system started as a result of the damages caused to unborn babies by the then new drug, thalidomide.

The collection of adverse reaction reports about a drug gives indications or trends that a drug may cause problems that were not detected in the pre-marketing trials. It is these trends that result in further investigations into a drug and perhaps the issuing of new warnings or even the removal of a drug from the market. For example, this reporting system in the US picked up cases of pancreatitis in people taking Byetta and the severe allergic reactions in people using NovoRapid both of which resulted in increased warnings being issued.

It is estimated that there is a 90% under-reporting of adverse reactions but nevertheless, the system gathers information that helps to protect the health of the public.

**Adverse reactions to prescribed drugs cost the NHS £2 billion – the pharmaceutical industry needs better regulation and to be held to account**

It is estimated that the cost to the NHS of adverse reactions to prescribed drugs is £2 billion – and this figure could be higher if it included adverse reactions that occur with drugs that are prescribed to people while they are actually in hospital!

- 6.5% of total hospital admissions in the UK are due to adverse drug reactions

The sums are simple, it is only the numbers that are large! In 2006 the total number of hospital admissions was 16,000,000 so 6.5% of this is 1,040,000. The calculated cost of a day in hospital is £228 and on average people admitted with adverse drug reactions stay in hospital for 8 days. Thus the total cost to the NHS for adverse drug reactions

could be as much as £1,896,960,000 for hospital admissions alone. [Adverse Drug Reactions as Cause of Hospital Admissions, BMJ 329 15-19] Not included in these costs are adverse reactions that are treated without hospital admission.

These are just hard facts and figures but we must not forget that 1,040,000 hospital admissions are real people who have been made unnecessarily ill as a result of a prescribed drug.

- Action being led by MP, Jon Trickett on behalf of pressure group Compass

Jon Trickett MP has asked Parliamentary Questions about the numbers and costs of adverse drug reactions. Compass has launched an investigation into the role of the pharmaceutical industry and public health which will explore key issues including:

- The relationship between the pharmaceutical industry and public health
- The current system of drug regulation
- The safety and efficacy of drugs
- Whether it is in the public interest for drug companies to be represented by the Department of Health.

It will also review the progress made since the 2005 Health Committee report, 'The Influence of the Pharmaceutical Industry', to which IDDT gave evidence of our concerns about the power and influence of industry in diabetes treatment and research.

Zoe Gannon is leading the research and has made some important points.

- The lack of effective regulation of the pharmaceutical industry is costing the tax payer, and in some cases is also causing unnecessary suffering.
- The pharmaceutical industry has an important role to play in the economy but companies are making huge profit margins in excess

of 14.3% against a normal business average of 4.6%!

- The pharmaceutical industry is always promising the latest miracle drug but too often fails to deliver. The number of truly new drugs is decreasing yet tax payers' money is funding questionable research and development expenditure.

All of this suggests that unlike other industries, the pharmaceutical industry makes a great deal more profit yet is producing fewer new drugs and those that are being made, produce greater numbers of adverse effects that risk harming people. For this privilege we tax payers are paying the price!

Readers may remember that the Health Committee report recommended that the pharmaceutical industry should be regulated by the Dept of Trade and Industry, as are other industries, and all health matters, such as drug regulations, should be handled quite separately by the Dept of Health. This still seems the most effective way of taking at least some control over the pharmaceutical industry and would result in greater transparency and less suspicion of conflicts of interest.

### **How to report adverse drug reactions through the Yellow Card Scheme**

For many years, only doctors could report adverse reactions but the system has been expanded so that patients and other health professionals can now make reports. You can report any suspected adverse reactions you experience. You only have to suspect, not prove, that adverse effects are caused by a drug.

- If you have access to the internet: go to [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk) and CLICK on submit a Yellow Card report. On this site you can also check the adverse reactions reports already made.
- If you prefer to use a paper Yellow Card reporting form: telephone the MHRA on 0207 084 2000 or e-mail [patientreporting@mhra.gsi.gov.uk](mailto:patientreporting@mhra.gsi.gov.uk) and ask for a form to be sent through the post.

### **You can also check on adverse reactions already reported**

If you are considering a choice of treatment/ insulin or you think that you are experiencing an adverse drug reaction to insulin, it can be useful to look at the adverse reactions that have already been reported by doctors and patients. However, as the reports are of suspected adverse drug reactions, it does not necessarily mean that the drug actually caused them, just that it may have.

You can look at the reports by going to the same website: [www.yellowcard.gov.uk](http://www.yellowcard.gov.uk)

This website has had a major upgrade and so it gives a lot more information in a more comprehensive way. We will be looking at the adverse reactions for the various insulins, in the coming weeks and reporting in the January 2009 Newsletter. In the meantime, if you suspect you adverse effects to a drug or insulin, please report it. It improves the safety of medicines and helps to protect us all from adverse drug reactions.

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## **Diet - Have We Got It Right?**

### **Different types of sugar**

We know that there are different fats but an article in the New Scientist [25 June 2008] suggests that not all sugars are the same either. It has been shown that overweight adults who eat large amounts of fructose have had alarming changes in their body fat and insulin sensitivity that don't happen after eating glucose. Pure fructose is found in fresh fruit, fruit juice and preserves but we eat more of it than we think. Soft drinks contain high fructose corn syrup [HFCS] which gets broken down by the body into 55% fructose and 45% glucose. The same happens when we eat ordinary sugar [sucrose]. As long ago as 2001, an article in the New Scientist suggested that fructose was part of the cause of the increase in obesity and insulin resistance but there have been few investigations until now.

In research at the University of California 33 overweight and obese adults went on a diet of 33% fat, 55% complex carbohydrates and 15% protein for two weeks, then for another 10 weeks they went on a diet where 25% of their energy came from fructose or glucose. The results showed that:

- in people given fructose there was an increase in the intra-abdominal fat [fat that wraps round internal organs] causing increases waist measurements which has been linked to increased risks of Type 2 diabetes and cardiovascular disease. This did not happen in the group who ate glucose instead of fructose even though both groups put on the same amount of weight.
- The people who ate fructose also had raised triglycerides which are deposited as abdominal fat and cholesterol.

This study only looked at pure fructose and not high fructose corn syrup or sucrose so it is not yet clear whether these substances can be blamed for the increase in obesity and Type 2 diabetes but the researchers are planning a long-term study to find out. However they do say that it is not too soon for people with metabolic syndrome, the group of conditions that increase the risk of Type 2 diabetes and cardiovascular disease, to avoid drinking too many drinks containing fructose.

### **Looking into fruit and leafy vegetables also showed concerns about fructose**

A recently published study looking at the eating habits of 73,000 female nurses over a period of 18 years showed that an increase in leafy vegetables may reduce the risk of women developing Type 2 diabetes. [Diabetes Care, July 2008] For every additional serving of leafy vegetables the risk of Type 2 diabetes may be reduced by 10%. But interestingly, they found that total consumption of all fruit and vegetables was not associated with diabetes risk but what they did find was an 18% increased in the risk of developing Type 2 diabetes amongst those who drank a lot of fruit juice which of course, contains high levels of fructose.

### **Is it time for a re-think in the five a day recommendations?**

As fruit juice quickly raises blood sugars, it is not surprising that people with diabetes often use it to raise their blood sugars when hypo. The above research shows that fructose may be contributing to increased waist lines and the risk of Type 2 diabetes but fruit juice which contains fructose, is recommended as one of the government's 'healthy' five a day options! So is one of the five a day actually contributing to the cause of the very problem the five a day recommendations were designed to solve?

### **By the way...**

Mediterranean diet, again! A study published in the BMJ [online May 31, 2008] has suggested yet again that people who stick closely to a Mediterranean diet have a reduced risk of developing Type 2 diabetes. 13,380 people without diabetes were followed for over 4 years and the results showed that the people who stuck closely to the Mediterranean diet have a 83% lower risk of developing Type 2 diabetes than those didn't.

The traditional Mediterranean diet is rich in olive oil, vegetables, fruits, nuts, cereals, legumes and fish but relatively low in meat and dairy products. There are also studies showing that people with diabetes also do better on this diet. This sort of evidence has been around for many years so why do we have dietary recommendations for high carbohydrates?



## **We're Coming Up To Winter Again...**

As winter approaches, don't forget that people with diabetes are treated as a priority to receive 'flu jabs. While most people are aware of this, many people are not aware that they are also entitled to a free vaccination against pneumonia.

Recent research [Diab Care, August 2008] has shown that people with diabetes had a 26% higher risk of pneumonia-related hospitalisation

compared to those without diabetes - a 4.4 fold increased risk in those with Type 1 diabetes and a 1.2 fold risk in those with Type 2 diabetes.

The risk of pneumonia was greater with longer duration of diabetes and with longer duration with poor glucose control but even in people with 'good' control there was an increased risk of 22% compared with people without diabetes.

Just food for thought...

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## From Our Own Correspondents

### My experience of 'The Pill'

Dear Jenny,

I thought your readers may be interested in my experiences of taking the contraceptive pill. After 16 years of having Type 1 diabetes I was prescribed the contraceptive pill which I used for four years. I then had retinopathy in both of my eyes and required laser treatment. Only one doctor told me that 'the pill' may not be ideal for women with diabetes and I stopped taking the pill. Now 30 years later, after 50 years of diabetes, I have not had further retinopathy and I am still driving a car. I am very thankful to the doctor who saved my eyes. I hope my experience may help other women with diabetes.

J.K.B.  
Switzerland

### Changing to pork insulin in Australia

Dear Jenny,

I was worried that changing to pork insulin and that the suppliers, Aspen Pharmaceuticals, would be willing to supply small orders and how difficult all this would be but the short answer is that it all good news!

Aspen told me that the supply of non-licensed, specialised drugs is designed to help the patient as much as possible. My doctor obtained approval for pork insulin and gave me an order form to fill out the number of bottles I wanted. I faxed it to Aspen who delivered the insulin to my doctor within a day or so and I paid the invoice by credit card directly to Aspen. My first order was 2 vials of Hypurin Porcine Neutral and 2 vials of Hypurin Porcine Isophane.

Already I feel the action curves of the pork suit me better, my moods are better, my hypo awareness is less than with beef insulin but still very noticeable from 3.2 mmol/l.

So far so good and thanks to everyone for being so supportive.

Terry,  
by e-mail

**Note:** Terry thought his positive experiences might be of help to other people in Australia and is happy for people to contact him by e-mail at [tjmtoox1@yahoo.com](mailto:tjmtoox1@yahoo.com)

### Gluco Tabs in 'bulk'

Dear Jenny,

We discovered that Gluco Tabs are much easier to carry about because they are in a plastic case but they are so much more expensive than 'Dextrose' tablets that we didn't feel we could justify the expense as a family. Well, now Boots are selling 'bulk' packs of Gluco Tabs with a refill bottle of 200 of Gluco Tabs and so we are much happier to buy them. The cost comes down enough to justify having the reassurance that we won't find a stack of hard, moulded-together tablets at the bottom of the bag, because the wrapper isn't hardy enough. They're also available in Asda, I hear.

M.E, A Mum  
By e-mail



## **Your article on Aspirin**

Dear Jenny,

Following the article on aspirin in the July Newsletter, I would like to pass on my experiences. During the past few years I've had laser surgery for retinopathy several times. Two years ago my eye consultant said he couldn't understand why I kept having retinal bleeding which required laser surgery and said, "You're not taking aspirin on a regular basis, are you?" When I said yes on the instructions of my diabetic clinic, he contacted them immediately so that they could instruct my GP to discontinue prescribing it.

Within weeks that retinal bleeds stopped and I haven't had any since. Perhaps though this Newsletter you could suggest that your members check with their eye specialists before taking aspirin regularly.

I very much appreciate your Newsletter, it's the only thing that keeps me informed about animal insulin.

Mrs C.E.  
West Midlands

## **Responses to pumps and animal insulin**

Dear Jenny,

I am one of the people who uses animal insulin in a pump – I used Novo Nordisk pork insulin and now Wockhardt Hypurin Porcine Neutral with no problems at all. In fact, when I used 'human' and analogue insulins in my pump, I used to get blocked tubing quite often but this has never happened with pork insulin.

In cases where people have who doctors are unhappy to allow them to use animal insulin in pumps, I wonder if they would get if they could refer their consultant to talk to another consultant who already has experience of patients using animal insulins and a pump?

L.B.  
By e-mail

Dear Jenny,

After 57 years of diabetes [badly controlled for many years] my partner has had an insulin pump for over 4 years and feels much better than he did when he was injecting. The only type of insulin that works for him and that he can tolerate is pork, so he uses Hypurin Neutral. He has never had any problems with his pump, but we have had to develop a different strategy from that which pump-users generally use, because of the 3-4 hour time to peak action with this insulin. We rely on a carefully calibrated basal rate that matches as precisely as possible his insulin requirements over 24 hours, and check his blood sugar at least 4 times a day to determine when, and how much, carbohydrate he should eat. Rather than have large meals, he grazes throughout the day. This keeps his energy levels more even.

The result of this has been a slow but steady decrease in his insulin requirements (down to about 50% less than when he was using injections), an improvement in his HbA1c to the point that his doctors are delighted with him and the general improvement in his health. We wholeheartedly recommend insulin pumps and would be happy to share our experience of programming the pump for pork insulin. We can be contacted by e-mail [am@eternalforest.org](mailto:am@eternalforest.org) or by phone on 01758 612006.

Glad to see IDDT continues to go from strength to strength!

Arabella Melville

## **Massage therapy has made a big difference**

Dear Jenny,

I find your information very interesting. I have had Type 1 diabetes for 42 years, since I was 9 years old. All my joints and muscles have become extremely stiff and painful. I have been tested by numerous doctors but have no concrete diagnosis. Over a year ago I started massage therapy on a weekly basis and over the months I have steady and significant improvement and I would recommend massage

therapy to anyone with similar problems as I feel so much better.

Mr G.J  
By e-mail

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## 'Modern' Insulins - Fascinating!

I know I've mentioned this before but I'm like a dog with a bone! I'm fascinated to know why Novo Nordisk always seem use the term 'modern' insulins when referring to their analogue insulins and never actually call them 'analogues'. I have heard 'modern insulins' used by representatives of Novo Nordisk, seen it their press releases and looking at their financial report for the half of 2008, yes, there it is again: "Sales of modern insulins increased by 30% (21% in Danish kroner)." The report referred to their other products by name eg NovoSeven®, so why not refer to analogue insulins by name?

Then on September 9th, the very day I was about to send this Newsletter to the printers, Novo Nordisk issued a press release and how did it describe NovoMix 30?

*"NovoMix® 30 (biphasic insulin aspart) is a premixed, dual-acting modern insulin, indicated for the treatment of diabetes mellitus, which contains both rapid-acting insulin (30%) and intermediate-acting insulin (70%)."*

Nowhere does it tell readers that NovoMix 30 is an insulin analogue!

The word 'modern' means little – is it modern as opposed to ancient, as in history? English grammar fanatics would say that it is an adjective that describes the word 'insulin' but when used for a insulin, it tells us nothing and you can't even look it up to see what it is!

Other insulin manufacturers have no difficulty using the word analogue, so why is it a problem for Novo Nordisk to use it? By not referring to

NovoMix 30, NovoRapid and Levemir as analogues, are they trying to disassociate themselves from insulin analogues, when very justifiable questions are raised about their long-term safety? Are they preparing us for the time they remove all other insulins so that insulin is just insulin and the fact that is analogue made by GM technology gets forgotten? I have no idea, but it all seems strange and there must be a purpose as they are so studiously avoiding using the words analogue insulin! And what will they call the next generation of new insulins – ultra modern?

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## News From Australia

### **Type 1 diabetes is still on the increase in Australia**

A recent report by the Australian Institute of Health and Welfare, Incidence of Type 1 diabetes in Australia 2000–2006: first results, has shown that the incidence of Type 1 diabetes is rising at around 3% a year - high compared to other countries with:

- 6,000 new cases in children aged 0 to 14 years between 2000 and 2006, the equivalent of more than two new cases every day.
- The rate of new cases of Type 1 diabetes was highest in children aged 10 to 14 years, the rates for 15 to 24 year olds remained fairly stable but for people over 25, the rates fell.
- There were nearly 9,000 new cases of Type 1 diabetes in people aged 15 or over with males over 15 years almost twice as likely to be diagnosed as females of the same age.

### **Opinion formers in Australia**

Based in Victoria, the Type 1 Diabetes Network completed an on-line consultation that has resulted in the formation of an Opinion Leaders Group made up of people living with diabetes as well as parents, partners and families. It also includes representatives from various patient organisations. This new patient led panel of volunteers is expected to develop a statement of the issues affecting Australians

with Type 1 diabetes. Details can be found by visiting [http://www.d1.org.au/opinion\\_leaders.htm](http://www.d1.org.au/opinion_leaders.htm)]

### **Australia ahead of America as the world's fattest country!**

While America has been seen as having the highest obesity rates, with the UK not far behind, Australia has quietly taken over. With a population of 15.1 million, 26% of Australian adults are now obese compared to 25% of Americans. This puts Australia ahead of America as the world's fattest major country.

### **Websites revamped**

Diabetes Australia has revamped its website [www.diabetesaustralia.com.au](http://www.diabetesaustralia.com.au) to provide useful information to the public. The revamp was carried out after consultation with people with diabetes, the general community and health professionals, to ensure that the site delivers information based on their needs.

Funded by the Australian government but administered by Diabetes Australia, the National Diabetes Services Scheme (NDSS) website [www.ndss.com.au](http://www.ndss.com.au) has also been revamped to provide information 'to improve people's capacity to manage their diabetes'. The National President of Diabetes Australia, Dr Gary Deed acknowledged that the internet is a critical source of information and is increasingly a first point-of-call for people who are interested in researching a topic.

### **Protecting Women's health in Australia**

The Bridges Research Grant Programme is managed by the International Diabetes Federation [IDF] and funded by pharmaceutical company, Eli Lilly. BRIDGES supports worldwide diabetes research that bridges the gap between science and people with diabetes. The first round of funding has been completed and one of the projects being funded is in Australia. – called the STOP Diabetes Project. It will look at the alarming rise of Type 2 diabetes and gestational diabetes to try to identify the barriers to changing unhealthy lifestyles which will include trying to understand women's health beliefs, attitudes, perceptions of risk and their response to illness.

## **Support For Carers Announced**

Nearly six million people act as carers for relatives and this includes some family carers of people with diabetes. Complications of diabetes or total loss of hypo warnings can make a carer essential. But sometimes, 24 hour caring can just get people down and they need a break.

The government has now recognised this and is to double the amount of respite care available for family carers of the elderly and disabled. As part of a new 10-year strategy to inject £255 million, over the next two years £150 million will be invested to give carers the opportunity to take short breaks from their work.

- £38 million will go towards supporting carers in the job market, encouraging flexible working hours and job training. It is already the right of carers to request flexible working although only 7% of carers are aware of this.
- Young carers who care for sick parents and relatives will be granted an extra £6 million to go towards increasing protection from "inappropriate" caring for young people.
- Annual health checks for carers to maintain their physical and mental well-being will be piloted.
- There will be training for GPs so they are better able to advise on the pressures of being a carer.

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## **News From The Pharmaceutical Industry**

New pre-mixed insulin analogue - Novo Nordisk has received approval in the US for a new pre-mix analogue insulin. It is Novolog Mix 50/50 (insulin aspart protamine/insulin aspart) – Novolog is called NovoRapid in the UK. The approval says it is to improve glycaemic control in adults and children with diabetes. Presumably it will appear in the UK before too long.

### **EC approves Apidra for use in adolescents and children**

Apidra [also known as insulin glulisine] is a GM rapid-acting insulin analogue made by Sanofi-aventis. It is approved for adults but in July 2008 the EC gave approval for its use in adolescents and children 6 years and older. This was based on a 26-week open label trial [a trial where doctor and patient know which insulin is being used] in 572 children and adolescents with Type 1 diabetes where Apidra was compared to Humalog.

Apidra is available in a pen, the Apidra SoloSTAR, which allows doses from 1 up to 80 units in one unit increments – so good for people on large doses. It is designed to be given with once daily, long-acting analogue Lantus - also approved for adults and children 6 years and older. Apidra can also be used alone in insulin infusion pumps.

### **Novo Nordisk wins design award for safe needle device**

In the US the NovoFine® Autocover® has been awarded a 2008 Medical Design Excellence Award. It conceals the needle during injections and is for use with the Novo Nordisk Flexpen and other Novo Nordisk injection devices and is designed to reduce the risk of needle stick injuries and help people with diabetes who are needle phobia. It is currently being introduced in the US, UK, and some European countries.

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## **For The Men**

### **Testosterone deficiency in men with Type 1 and Type 2 diabetes**

It has been known for some time that men with Type 2 diabetes are more likely to have a deficiency of the male hormone, testosterone, but recent research has shown that the same is true for men with Type 1 diabetes. Testosterone plays an important role in men's health and deficiency of it can contribute to impaired performance, mood, and libido, as well as having an adverse impact on cardiovascular risk. The findings of a recent study suggest that this is a significant

and unrecognised problem among men with diabetes and the authors suggest that it requires greater attention from clinicians and scientists. They stopped short of recommending testosterone replacement therapy as the risks and benefits require much more study. [Journal of Clinical Endocrinology & Metabolism, March 25 2008 online]

### **Testosterone supplements for older men – are they any good?**

A study of 230 non-diabetic men aged 60 to 80 who took a small dose of testosterone found that they developed slightly more muscle mass and less fat compared to those not taking the hormone. [Jour Am Med Ass, Jan 08] In addition, it did not boost their bone density [to prevent osteoporosis] or mental functioning. However, the men taking testosterone supplements did improve their insulin sensitivity although their levels of 'good' cholesterol were lowered. The researchers suggest that testosterone supplementation does not have a net health benefit and eating healthy food and maintaining physical activity are the best way to maintain good health in old age.

### **Research looks at testosterone gel**

Studies in the UK have tested the effect of testosterone gel [Tostran] on 221 men with insulin resistance and low testosterone levels. On average the men were 60 years old and classed as obese. 80% had metabolic syndrome, 60% had Type 2 diabetes and 44% had both. They were randomly selected to use the testosterone gel daily or a matching placebo gel.

The study showed that in the group treated with testosterone there were significant improvements in insulin sensitivity which may help to improve cardiovascular and other diabetes complications. There was a significant improvement in erectile dysfunction after 6 and 12 months. Skin reactions were the most commonly reported adverse effects in both groups. The authors recommend a screening programme particularly for men with Type 2 diabetes. [The study was sponsored by the manufacturers of the gel.]

### **Erectile dysfunction drugs linked to risk for hearing loss**

The FDA in the US has warned health professionals that sudden

hearing loss has been reported in people taking erectile dysfunction drugs, Viagra, Cialis and Levitra. The warning was based on 29 adverse events reported. Hearing loss was temporary in 33% of men and in almost all cases in only one ear.

### **Diabetes may be damaging men's fertility**

Research [Human Reproduction, May 2007] compared DNA in sperm from men with diabetes and men without it. The researchers found more DNA damage in sperm cells of men with diabetes which is a possible sign of reduced fertility. Sperm damage has been associated with male infertility and couples with a history of miscarriages.

This small study at Queen's University in Belfast involved 27 men with Type 1 diabetes with an average age of 34 and 29 non-diabetic men of a similar age. The semen volume, sperm concentration, output, form, structure and ability to move appeared to be the same but there was much more damage in the sperm of men with diabetes.

The non-diabetic volunteers in the study were all men seeking fertility treatment who may also have more sperm damage than the average man so the differences demonstrated in this study could be even greater if compared to non-diabetic men without fertility problems. Further research is recommended.



## **For The Ladies**

### **Leading up to menopause**

We hear a lot from women who talk about how their diabetes control goes adrift when they are in the menopause but little seems to be written about the time leading up to the menopause. This is usually gradual and can last for 3 to 6 years during which time a woman can experience mild to severe symptoms including:

- hormone and mood swings

- weight changes
- fluid retention
- headaches
- memory problems

All of these can affect blood glucose control either because of weight gain or due to hormonal and stress-related blood sugar swings. So it is important to test more frequently to make adjustments to your insulin regime or eating patterns.

Hormonal changes may cause symptoms that are similar to those of hypos – rapid heart beat, flushed skin, so instead of assuming it is a hypo, it is sensible to do a test before eating/drinking something sugary.

**Pregnancy** - it is also important to remember that you can still become pregnant during this time and as we know it is much healthier for women with diabetes, and for babies, to have planned pregnancies. If you have stopped menstruating for several months your period can still reappear. Most books say that you should go an entire year without menstruating before you can assume that an unplanned pregnancy will not occur.

**Post menopause health risks** - when menstruation has stopped completely, the risk of heart disease increases, there is a reduction in the amount of calcium in bones and an increased risk of vaginal infections. So it is important to talk to your doctor about these effects to help you to reduce these health risks to a minimum.

Good advice seems to be: don't despair, all women have to go through this but eat well, be physically active and adjust your diabetes regime as necessary.



## Snippets...

### **The Olympic Games - how many people in China have diabetes?**

It is estimated that there are 35million Chinese with diabetes. It is predicted that this number will grow as the Chinese become financially better off. Novo Nordisk expect the number of insulin users to grow by 30 to 35% a year. They have invested \$200 million in China with the expectation that China will become their second biggest market in the next 15 years with the US remaining the first. Last year's sales in China grew to \$165million and the company already controls 76% of the insulin market, with Human Mixtard 30 being the most widely used. Eli Lilly has 15% of the insulin market.

### **Reheating spag bol may be good for you!**

Have you noticed that spaghetti bolognese often tastes better reheated on the second day? Well scientists have now found that reheating increases the health benefits of the tomatoes in the sauce. Tomatoes contain lycopene, a powerful antioxidant that can help to combat heart disease and diabetes.

Apparently multiple rounds of heating alters the structure of the lycopene so that it is more easily absorbed into the blood stream but adding a little extra olive oil is also essential to carry the lycopene through the gut walls. So far re-heated sauces made in the lab and tried on 12 volunteers have shown that the lycopene blood levels were 55% higher after eating the re-heated sauce.

### **Using ears to best advantage**

New research suggests that declarations of love, jokes or anger are remembered best when they are heard through the left ear. However, instructions, directions and non-emotional messages are better heard in the right ear. It is all to do with the two halves of the brain having specialised functions – the left side is more dominant and logic-based and the right side the more imaginative side. As the right side of the brain controls the left side of the body and vice versa, some research has shows that the left ear is the one in which we should whisper sweet nothings! It also appears that the right eye is better for processing

colours, the left cheek best for kissing and the left side is favoured for holding babies. [The Times Online, 25.4.08]

### **Frog's skin boosts production of insulin**

Researchers have discovered that a substance on the skin of a South American frog boosts the production of insulin. The substance is a peptide, a protein that protects the frog from infection. The researchers have made an artificial copy of the peptide and tests have shown that it has the potential to develop drugs to treat Type 2 diabetes.

### **Athletes find another use for Viagra!**

In sporting circles Viagra is known as Vitamin V indicating that it is commonly used by athletes to boost performance—athletic performance that is! A similar drug to treat impotence, Cialis is also being used and apparently these drugs are regularly found in urine samples of male athletes. Experts believe that these drugs may increase blood supply to the muscles which may be helpful in sprinting. They may also enhance endurance by increasing blood flow to the lungs which gives athletes an advantage when competing at high altitudes or in polluted areas such as Beijing. There is also a suspicion that it is used by athletes who use steroids to build up muscles and steroids can lead to impotence. The World Anti-Doping Agency is conducting research which could mean that Viagra will be added to the list of illegal substances in sport.

### **More people having cosmetic and weight reduction surgery than ever before!**

Recent information from the British Association of Aesthetic Plastic Surgeons show that the number of surgical procedures performed in 2007 was 12% higher than in the previous year. The increase was not limited to women – 18% more procedures were carried out in men. The largest increases were in anti-aging procedures, facelifts and eyelid surgery. In the US almost 12 million cosmetic surgery procedures were carried out in 2007 – a 59% increase from 2000!

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

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## From Your Editor – Jenny Hirst

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