Insulin Dependent Diabetes Trust

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2007 - ‘Making Patient Choice A Reality’

I’d like to take this opportunity to wish all our readers a Happy and Healthy New Year. It’s a time for reflection on the past and looking forward to the future. Looking back to our formation in 1994, I see a small group of like-minded people getting together to try to maintain a choice of insulins to suit all needs and to seek recognition of the fact that some people cannot tolerate synthetic insulins and need natural animal insulins - real insulin. And I make no apology for the use of the word ‘real’ - if Novo Nordisk can refer analogues ‘modern insulins’, we can call animal insulin ‘real insulin’, because it is!

At the beginning of 2007, I see IDDT as an organisation that has grown beyond our wildest expectations, although I’m not sure that in 1994 we had any! The growth happened as a result of being entirely focussed on our aims, aims that have not changed over the years and will not change in 2007:

- **To help and support people with diabetes and their families, especially those having difficulties with synthetic insulins.**
- **To seek recognition that some people have adverse reactions to synthetic insulins and ensure that natural animal insulins remain available for them.**
- **To ensure that people with diabetes have an informed choice of treatment, including risks and benefits of all types of insulin.**

Perhaps the most important decision we made was that IDDT would never accept funding from the pharmaceutical industry. This makes us quite unusual in the charity world but we believe that it gives us credibility, independence and freedom. Of course, we will not grow as fast as other charities but of greater importance is that our messages are uninfluenced, and can be seen to be uninfluenced, by our funding sources. We have no conflict of interest and our responsibility is entirely to you, our members, readers and to people who live with diabetes.

So where are we going in 2007?

The discontinuation of Novo Nordisk pork insulin and the start of the discontinuation of their synthetic 'human' insulin will result in a severe reduction in choice of insulins. It means that people who have adverse reactions to human or analogue insulins will have fewer alternatives - amazing that this can happen when it is accepted amongst the medical and scientific community that every drug can cause adverse reactions in some people!

In many countries people are already denied a choice of insulin and are being forced to import insulins from other countries, just to stay alive. At a time when the message of governments in the developed world is 'patient choice', it is almost unbelievable that the pharmaceutical industry can have strategies that fly in the face of the policies of governments. But more than this, it shows where the power actually lies and this is not with governments, not with the medical profession and not with patients but with the pharmaceutical industry! We know that governments take the view that they cannot interfere with the commercial decisions of pharmaceutical companies but they could publicly deplore their actions and they could publicly support patients in their needs. When your treatment is dictated by industry and not by scientific evidence, not by you and not by your doctor, then the time has come for people with diabetes to unite and act together.

These latest threats to choice of insulin has brought together people and organisations in countries across the world. In 2007 IDDT will be the flagship for people and organisations who believe that the needs of all people with diabetes are important and that choice of insulin must remain available to answer these needs. We will stand up and resist the influence of the pharmaceutical industry on our treatment - I don't know if we will succeed against their might but we will certainly try!

So our goal for 2007 is: 'Making patient choice a reality'.

2007 - New 'Good Medical Practice' Guidelines For Doctors Should Help Patients and Our Goals

A new edition of 'Good Medical Practice' issued by the General Medical Council [GMC] came into effect on November 13th 2006. It is a document that lists the duties of a doctor and also an explanation of what it means to be a good doctor. Some duties of a doctor do not change over time:

- always put patients first
- maintain a good standard of care
- treat patients as individuals, show respect and respect their dignity
- be honest and trustworthy
- keep up to date with knowledge and skills

But others mean that doctors will have to think differently:

- They have to protect and promote individual and public health.
- The nature of the relationship between doctor and patient is now a partnership and not a relationship. Doctors must listen to patients and respond to their concerns and preferences, not merely respect those preferences.
- The doctor should do more to support self-care.
- They must give patients the information they ask for, not just what the doctor thinks they want or need.
- Doctors must respect patients' rights to make decisions with them about their treatment and care ie patients should be part of the process of reaching decisions instead of just being involved in those decisions.
- Doctors will always be held personally accountable for their

actions. They must not only recognise but also 'work within' the limits of their competence.
- Effective treatments must be 'based on the best available evidence'.

What does all this mean for patients?

It means that as patients, we are no longer passive beings who unquestioningly receive treatment and information doctors choose to give us. It gives us power and rights within the relationship with our doctors. It categorically states that the treatment we receive is to be based on best available evidence - not beliefs, not assumptions, not on what the last drug rep said but on the best evidence from research. It also means that we can ask what that evidence is because doctors must give us the information we ask for.

It recognises all that IDDT has been advocating and it has very real significance for the people who have difficulties convincing their doctors that they want to change to, or continue to use natural animal insulins.

Just an anecdote...

Just before this new guidance came out, one of our long-standing members who has had diabetes for nearly 50years went to her diabetes clinic at a large, well-known hospital. Some years ago she had about 10years on synthetic human insulin and after feeling dreadful, having lots of hypos with reduced warnings, she changed back to the animal insulin she had used previously and for the last few years she has been fine. But at this clinic visit, her consultant simply told her he was changing her to synthetic analogue insulins. She explained that she had no wish to change and gave reasons for this but after some discussion, the consultant got angry, ignored her wishes and filled in one of a pile of forms on his desk for the diabetes specialist nurse to change her to Levemir.

Why was the consultant angry? Was it simply that our member was refusing to do as she was told? Was it that she asked for evidence to support his decision to change her to analogues insulins and maybe he didn't have any? Was it that his hospital has decided that people with diabetes should all be treated with the same insulin and here was one lady with 50years experience of living with diabetes who was refusing to unquestioningly accept this policy?

We will never know the answer, but the new 'Good Medical Practice' guidelines mean that this consultant, and doctors like him are going to have to change their thinking, their approach and their attitude. While these are guidelines, any doctor who fails to follow them risks being reported to the General Medical Council, not a prospect relished by any doctor.

The new 'Good Medical Practice' guidelines probably give you more rights than you have ever had before.

The increasing discontinuations of various insulins by the major manufacturers mean that people with diabetes are being 'forced' to change their insulin. The heavy marketing of insulin analogues all too often means that they are not given a choice, but choice is still available. So IDDT's message to you is:

- Ask questions to find out the information you want or need.
- If you are unsure about the effectiveness or the possibility of adverse reactions to the treatment being recommended, ask for the best available evidence that supports that recommendation.
- If insulin analogues are being recommended, ask for independent evidence about their long-term safety.
- Being part of decision making about your treatment and care ultimately means that you have the right to refuse a treatment if you wish.
- Don't be afraid of standing up for yourself - it's your health and your life.

Lantus, Not Peakless After All!

I received an advert from the manufacturers of Lantus [insulin glargine] through my e-mail system a few days ago. This is annoying in itself but it was interesting that the 24hour insulin that has been sold on the basis of being a flat, peakless basal insulin is now advertised as having ‘no pronounced peak’. This is does not mean the same thing - it means that the peak is not pronounced, not that there isn’t one.

This could offer an explanation for the hypos at odd times that members have reported to IDDT when using Lantus.

NHS News

July 7 2006, NHS staff ‘not reporting errors’ - the NHS has “no idea” how many people die each year from hospital accidents or failed operations, according to the House of Commons public accounts committee. Their inquiry into patient safety found that in 2004/05, 974,000 ‘patient safety incidents’ and near misses were recorded by NHS trusts. It also noted that the NHS has developed a more open reporting culture but an average of 22% of incidents still go unrecorded - typically those incidents are medication errors and incidents leading to serious harm.

In 2000 the chief medical officer concluded that about 50% of incidents could be avoided if lessons from previous accidents and mistakes had been learned. In the light of this, the National Patient Safety Agency [NPSA] was set up but this latest inquiry concluded that the NPSA had made an “extremely weak” contribution to safety and value for money!

National survey of NHS services - as part of the Healthcare Commission’s job to ensure that services are designed around patients’ needs, every Primary Care Trust is carrying out a survey of randomly selected patients. If you receive one, make sure you fill it in as it is one way of getting your voice heard.

NICE Guidance for Type 2 diabetes - the National Institute for Health and Clinical Excellence (NICE) plans to publish its guidance on type two diabetes, including footcare, in July 2008. Further information can be found on NICE’s website at www.nice.org.uk

NHS closures - the new chief executive of the NHS plans a wave of hospital department closures. David Nicholson, the man responsible for leading the implementation of reforms, told the Guardian there would be up to 60 “reconfigurations” of NHS services, affecting every strategic health authority. Nicholson identified accident and emergency departments, paediatrics and maternity services as areas where provision would have to be overhauled.

NHS IT system fails 110 times [Sept 2006] - Computer Weekly magazine reported that the government’s £12.4bn NHS IT programme has broken down 110 times in the previous four months. The Times [May 30 2006] reported that the computer system designed to give every NHS patient their own medical record is running at least two and a half years late. This was confirmed by Health Minister, Lord Warner who also confirmed that the cost is likely to be nearer to £20billion than the original £6.2billion. In the meantime the bill for management consultants to help control spending in the NHS has risen from £221million to £777million!

NHS patients and staff reap rewards of GP Incentive Scheme - the results of the GP Incentive Scheme suggest GPs are providing a wider range of services indicating that GP practices are offering patients a high level of clinical and non-clinical care. Each practice on average achieved 96% of the points available [1011 out of a possible 1050] and will receive on average £125,900. Much of this money will be re-invested into NHS GP services, such as extra practice nurses. Practices have also taken on more staff, expanded services, and organised community nurses to visit people in their own homes. Over time it is expected that this will help the NHS to tackle health inequalities by targeting those at risk and focusing resources appropriately - time will tell...

Expert Pharmacists get the go ahead - in September 2006, the Health Minister announced that pharmacists with special interests in long-term conditions - such as diabetes, will now be given to opportunity to become 'experts' . They will have to undergo extra training and become accredited, before becoming a 'Pharmacist with a Special Interest' (PhwSI). It is intended that these pharmacists [PhwSIs] will be able to deliver more services, such as specialist diabetes clinics to help patients manage their medicines and condition. It is also intended to give people more choice about where, when and from whom they seek healthcare advice and treatment but those who need or choose to see their GP will still be able to do so.

Research News

Blind mice see again after retinal cell transplants [November 2006]
Researchers in the US and London's Moorfield's Eye Hospital have restored the vision in blind mice by transplanting light-sensitive cells into their eyes. The mice suffered from photoreceptor loss which occurs in many eye diseases, such as macular degeneration. The photoreceptors are specialised light sensitive cells that line the back of the eye [the retina] and are essential for sight. Previous studies using stem cells failed to restore sight because the stem cells did not form into photoreceptors. So in this research, the transplanted cells were at a later stage of development towards becoming photoreceptor cells. The researchers thought that the mature retina did not have the ability for repair but now believe that the first human retinal transplants could take place within the next decade.

Stem cells to repair defective insulin-producing pancreatic cells responsible for diabetes in mice. [Proceedings of the National Academy of Science, Nov 2006]

Researchers from New Orleans' Tulane University have used stem cells from human bone marrow to repair defective insulin-producing pancreatic cells responsible for diabetes in mice. Stem cells are immature cells which have the capacity to turn into any kind of tissue in the body.

The mice had high blood glucose levels and damaged kidneys and the treatment also halted the kidney damage. One group of mice were injected with stem cells. After three weeks they were shown to be producing higher levels of mouse insulin than untreated mice and had lower blood sugar levels.

The researchers do not know whether the kidneys improved because the blood sugar was lower or because the human cells were helping to repair the kidneys but suspect the human cells were repairing the kidneys in much the same way they were repairing the insulin-producing cells in the pancreas.

They are planning to carry out trials in people with diabetes whose kidneys are beginning to fail to find out whether giving the patients large numbers of their own adult stem cells will lower blood sugar, increase production of insulin and improve the function of the kidney.

Needle Phobia

By Beverley Freeman

The advent of inhaled insulin raises the issue of needle phobia, something that has not been addressed in previous Newsletters

What is a phobia?
According to the Cambridge International Dictionary of English a phobia is 'extreme fear of a particular thing or situation, especially one that cannot be reasonably explained'. A phobia is an irrational fear that has no logic and is given very little understanding. It is not

defined as a mental illness and it certainly is not a lack of will-power, moral-fibre or determination. It is estimated that 12% of the population will experience a phobia at some point in their lives

The NHS Direct website suggests that phobias usually develop in late childhood, adolescence or early adult life in response to a frightening event or situation. However, it is not always clear where phobias come from.

Needle phobia

Needle phobia is known as Belonephobia and injection phobia is known as Trypanphobia. The symptoms of both vary from shortness of breath to feeling nauseous and being unable to speak or think clearly. True needle phobia as opposed to 'not liking needles' is quite rare.

Needle phobia can cause embarrassment, undermine self-confidence and cause misery if you have diabetes that requires insulin injections. So what can people with diabetes and needle phobia hope for? Maybe inhaled insulin could be the answer but it could be argued that doctor's budgets would be better invested on curing the phobia itself as opposed to finding a new tool that merely puts off solving the problem.

Treatment for phobias

The irrational nature of a phobia means many people do not seek professional help but it is a problem that can be fixed with the correct professional advice and support. The treatments mainly used are talking and listening treatments known as psychotherapy, these include cognitive behavioural therapy and behavioural therapy.

Cognitive therapy - according to the Royal College of Psychiatrists, emphasises the important role of thinking about how we feel and what we do. The treatment involves identifying how the negative thoughts about needles or injections affect us and then looks at ways of tackling or challenging those thoughts with the aim of changing our thinking patterns about our phobia. Cognitive therapy encourages discussion of how we think and helps us to get rid of the destructive views we have about injections and needles. It tends not to focus on the past but on a more positive present and future relationship with your phobia.

Behavioural therapy - again according to the Royal College of Psychiatrists, seeks to improve the way a person feels about needles and injections. This is done by changing what they do to cope with the phobia. Behavioural therapy tries to change patterns of behaviour. People can be helped to overcome phobias by spending more and more time in the situation that the phobia is triggered and learning ways of reducing the anxiety. Homework or exercises may be given, keeping a diary and practising new skills between sessions are all part of behavioural therapy.

What you need to know

Any form of psychotherapy involves regular meetings and the length of treatment should be agreed between the client and the therapist. What happens in those sessions is considered confidential. You can be referred by your GP to a qualified psychotherapist. It is important that a psychotherapist has a recognised qualification and your GP should ensure this before making a referral. Do not be afraid to shop around if you do not get on with the first psychotherapist you see as it is very important that you feel comfortable.

Helpful Websites: www.bps.org.uk The British Psychological Society

www.bacp.co.uk British Association for Counselling and Psychotherapy.

www.needlephobia.info and www.needlephobia.com

The Artifical Pancreas - Progress For Type 1 Diabetes

Scientists in Cambridge are developing a device being called an artificial pancreas. It uses an existing type of glucose sensor and an insulin pump and the researchers have found a way that enables the two to communicate with each other. So the system will be able to measure blood glucose levels every minute, transmit the information to a hand held computer which will then calculate the amount of insulin needed. The insulin pump then delivers the required dose of insulin. The artificial pancreas looks like a pager and can be clipped to a belt. Trials in youngsters are set to begin in January 2007 at Addenbrooke's Hospital.

This is a really positive step forward for children and adults with Type 1 diabetes and something that we have been awaiting a long time. It is estimated that with the present insulin injection regimes blood glucose levels are normal for only about 30% of the day. However, it is hoped that with the artificial pancreas, this will rise to 75% of the day so reducing the risk of long-term complications and on a daily basis reduce the numbers of hypos.

Bits and Pieces About Drugs

What does off - label mean?
All medicines have to be assessed by the drug regulatory authorities before they are approved and given a marketing licence. A drug can be approved for a variety of illnesses or specific groups of people and the manufacturer has to apply for each condition and group of patients.

If a doctor prescribes a drug for people for a condition for which it is not licensed or who are not within the ages for which it is licensed, the medicine is being used 'off-label'. Examples in the UK:

- Lantus is not approved for use in children under 6 years old
- Inhaled insulin is approved for adults with Type 1 and Type 2 diabetes but not children.

Doctors who prescribe off-label medicines could face liability problems if the patient experiences adverse reactions. If you are prescribed a medicine off-label then you should be informed of this, the possible risks, that there is uncertainty about its effect and that the medicine may not have been tested for your condition or age-group.

Note: just because a drug is licensed for specific uses in one country does not mean that the same will apply in other countries, so a drug could be off-label in one country but not in another.

Concerns Over Doctors' Prescribing Skills

Deaths due to adverse drug reactions have risen by over 500% since the early 1990s costing the NHS an estimated £500million a year. In July 2006 the General Medical Council [GMC] was criticised for failing to put a greater emphasis on pharmacology in UK medical schools, especially important with the rise in use of more complex medicines. It is suggested that many doctors lack the sufficient knowledge to prescribe drugs properly. The GMC have denied the allegations and insisted that most of a doctor's knowledge about how and what to prescribe was learned "on the job."

- Professor Sir Mike Rawlins, chairman of the National Institute for health and Clinical Excellence, [NICE] said: *"A great deal of mis-prescribing is because of a lack of knowledge. About 80% of adverse drug reactions are avoidable. In the most serious problems, people suffer and a proportion die because drugs are not used properly".*
- Professor Jeffrey Aronson, president-elect of the British Pharmacological Society, insists that risks to patients *"could be prevented by careful prescribing, by careful use and by increased knowledge on the part, both of doctors and nurses and pharmacists who are prescribing drugs, and the patients who are using them."*

More Attention Needed To The Safety of Drugs

A report commissioned by the Food and Drug Administration [US drug regulatory organisation] published in September 2006 called for “substantially increased resources” in funds and personnel for the agency. The report stated that the FDA needs to pay more attention to the safety of drugs once they are already on the market. The report also recommended that new pharmaceutical products should carry a special symbol to warn that not all side effects are known, and that the FDA should evaluate all safety and effectiveness data for new drugs within five years of their approval. This seems like an excellent idea that should be adopted throughout the rest of the world!

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Report Side Effects From Your Medicine on a Yellow Card

A message for you from the Medicines and Healthcare products Regulatory Agency (MHRA):

“If you think a medicine has caused a side effect or reaction, you can report the problem to the MHRA through the Yellow Card Scheme. This scheme has been used for over 40 years to collect information on suspected side effects from all types of medicines. These include prescription medicines, medicines you can buy without a prescription as well as herbal and other complementary remedies.

“Even if you are unsure whether a medicine or combination of medicines has caused a side effect, please complete a Yellow Card. To download a copy or to complete online go to www.yellowcard.gov.uk Alternatively forms can be found at pharmacies, other NHS outlets or doctors’ surgeries. You can also call the Yellow Card hotline on free phone 0808 100 3352 weekdays between 10.00 am and 2.00 pm.

“You can help to make medicines safer for everyone by filling in a Yellow Card about a suspected side effect. The MHRA is the government agency responsible for ensuring that medicines and medical devices work and are acceptably safe. No product is risk-free. Underpinning all our work lie robust and fact-based judgments to ensure that the benefits to patients and the public justify the risks. We keep watch over medicines and devices and take any necessary action to protect the public promptly if there is a problem.”

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After 15 Years Pork Insulin Returns to Australia!

Novo Nordisk discontinued pork insulin in Australia in 1991 and as in the UK and many other countries, there are Australians who are unable to tolerate synthetic human insulins. Until now they have been importing it at a high costs and risks of it being damaged due to the high temperatures. So I am delighted to tell you that Aspen Pharmaceuticals has reached an agreement with Wockhardt UK so that Aspen will be able to supply pork insulin to people in Australia. This will still take place through the Special Access System. At the time of writing this Newsletter the necessary paperwork has not been completed but I can tell you the TGA [the regulatory authority] has agreed in principle.

Beef insulin has always been licensed in Australia and Wockhardt Hypurin Bovine insulins have been supplied through Aspen Pharmacare. Aspen is going to hold stocks of Wockhardt pork insulins and the first delivery to them is expected March/April 2007. Even better news is that Aspen intend to sell porcine insulin at a much lower price than the one people are paying at the moment. They have also assured us that they will continue supplying animal insulins as long as they are available and as long as there is a need for them, however small this need may be.

This is largely due to the care and concern from one man in Aspen and it has been a moral and ethical decision, not one based on profit, so to him and all those at Aspen, we say a huge thank you. Thank you too to Larrane, Michael, Ian and Kathie who are IDDT's key people in Australia who have never given up the struggle to ensure that people in Australia have the insulin they need and the choice they need.

There will be more details in our next Newsletter and on IDDT-Australia's website: go to www.iddtinternational.org and click on IDDT International.

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Information! Information! Information!

The European Commission to revisit advertising of drugs to the public

As readers may remember IDDT joined the ranks of those objecting to direct-to-consumer advertising [DTCA] of prescription-only drugs by the pharmaceutical industry. The main reason is clear - advertising is out to sell a product and therefore adverts are biased in favour of a product and where drugs are concerned, the public needs to know about the adverse effects of drugs as well as their good points. This is simply not possible in the time allocated to a TV advert.

Except for the US and New Zealand there is a ban on DTCA and in 2004 a proposal to remove or weaken this ban in the EU was overwhelming rejected by the EU Parliament. But only two years later, in a speech to the Pharmaceutical Forum, the Vice-President of the European Commission responsible for Enterprise and Industry said the Commission 'openly regrets' this decision. He called for a reform of the European pharmaceutical products' legislation. In other words they want to re-open the debate on direct-to-consumer advertising.

On September 29 2006, the European Commission established a body, the Pharmaceutical Forum, to address public health issues including the review of pharmaceuticals. The Forum includes many representatives from the pharmaceutical industry who obviously have a vested interest in wanting DTCA - they will sell more drugs!

It has become clear that there is an underlying shift to revisit direct-to-consumer advertising, under the pretence of discussing "information" to patients. When confronted about the crushing defeat of the previous commission proposal to introduce DTCA, MEP Forum member, Dr. Chatzimarkakis firmly replied that "70% of the current MEPs were new to their positions". In other words, he sees an opportunity to reopen the debate simply because new MEPs were not involved in 2004.

IDDT will continue to support the position of Health Action International [Europe] which is that due to inherent conflicts of interest which put sales and profit above public health, the pharmaceutical industry is in no position to provide the information people want, need and deserve; this has to be information that is unbiased, reliable and comparative.

'Information Prescriptions' by 2008

The Government White Paper, 'Our Health, Our Care, Our Say' 2006 contained a commitment to introduce Information Prescriptions for everyone with a long term condition or care need by 2008.

What exactly are Information Prescriptions?

The White Paper describes them as *'a means of providing people with conditions such as diabetes, with information about their condition, their treatment options and how and where to seek information about services that are appropriate to their needs at the time.'* Indeed, this is everything that IDDT has been lobbying for, especially the recommendation that people are provided with information about their treatment options! For people with insulin-requiring diabetes, this can only mean information about ALL the various types of insulin and the various insulin regimes eg how many daily injections are necessary with various insulins.

So to the many people that are not given information about ALL their insulin choices and to those who are refused the choice of natural animal insulin, IDDT says: ***the Government White Paper supports***

your right to information about treatment options, so use it, quote it and insist on your rights.

Implementation

If the White Paper is to be implemented by 2008 for the 2 million people with diabetes, there is a lot of work to be done by a lot of people! Whether or not an Information Prescription can fill the gap in basic knowledge about diabetes remains to be seen but it is a start. It certainly should encourage people to ask questions about their treatment and their options and it should encourage health professionals to see this as a positive step forward and not in any way threatening.

Discussions have begun in a coalition between Diabetes UK, the Association of the British Pharmaceutical Industry [ABPI] and Ask About Medicines at a meeting on October 13th. Sadly IDDT was not invited to the meeting but two IDDT members were present. The coalition concluded that everybody with diabetes has a right to expect:

- A personalised information prescription expressed in an appropriate format as part of their care planning process
- That everyone involved in their care knows what information they have been prescribed
- Access to clear and consistent information that is accurate, up-to-date and trustworthy to enable people with diabetes to understand their condition and treatment options regardless of their age, ethnicity, disability or postcode
- Encouragement to seek information on medicines and other treatments by discussing their condition with, and asking questions of, a range of healthcare professionals or other forms of support.
- Information tailored for each person in his/her particular situation.

IDDT just has some niggling concerns…..

- The meeting in October 2006 about Information Prescriptions was hosted by the Association of British Pharmaceutical Industries [ABPI]. Why and what is the pharmaceutical industry's involvement in Information Prescriptions? Information that is of value to patients has to be independent and unbiased and therefore should not come from the industry that has a vested interest in selling insulins or drugs.
- Who is going to meet the cost of providing Information Prescriptions to the millions of people with chronic conditions? The cash strapped NHS or is this where industry comes in?
- Forgive the suspicions, but is there a connection between the move in Europe to bring in direct-to-consumer-advertising as direct-to-consumer-information?

For patient Information Prescriptions to provide 'clear and consistent information that is accurate, up-to-date and trustworthy', there is no place for pharmaceutical industry involvement. Information Prescriptions must be based on reliable information from independent, high quality reviews of the evidence. The article below provides sufficient reason for this view.

The quality of the information we receive

As readers know, IDDT has long been concerned about the quality of the information we receive to inform our choices. The best evidence is found in high-quality reviews which look at all the studies into a drug or treatment and from those that meet standards of good quality research, conclusions are drawn - Cochrane Reviews are classed as the gold standard. The other way to provide reliable evidence is to use a system of meta-analysis which combines results from multiple studies of the same drug.

Peter Gøtzsche and his team at the Cochrane Centre in Copenhagen, compared reviews funded by pharmaceutical companies with similar reviews without industry funding. Compared to independent reviews, they found that reviews supported by industry are less transparent and tended to recommend the experimental drug without reservation. Those studies conducted without drug industry funding reached similar conclusions to the systematic reviews on the Cochrane database, the gold standard. The authors conclude that industry-supported reviews should be read with caution. Gøtzsche says he would now ignore any meta-analyses funded by drug companies. [BMJ, 15 October 2006]

How does this relate to research into insulins? Well, we have already pointed out that of the studies included in the Cochrane Review of short-acting analogues, over 80% were funded by insulin manufacturers and the funders of the remaining studies were not declared, so the vast majority of the studies were funded by industry. So we can draw our own conclusions!

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People with Diabetes Are Left in the Dark, Putting Their Physical and Emotional Wellbeing at Risk

Diabetes Information Jigsaw Report - by the Association of the British Pharmaceutical Industry [ABPI], Diabetes UK and Ask About Medicines, July 18th 2006

This report revealed that the majority of the two million people diagnosed with diabetes in the UK are unaware of the dangers of not managing their condition properly and are lacking significant information.

The key findings of the report are:

- over a third of people with diabetes don't know they will have the condition for life and half don't know that diabetes can reduce their life expectancy.
- 32% don't realise heart disease is a common complication of diabetes.
- over 60% of pregnant women with diabetes do not realise that stillbirth is a possible outcome of their condition not being managed appropriately during pregnancy, or that their baby could be born with difficulties.
- 65% of people with diabetes are not taking their medications as prescribed
- 33% don't understand what their diabetes medications are for or how to take them because they feel stupid asking questions and 57% find it difficult to ask questions. They feel there is not enough time during the consultation or their doctor seems too busy
- most importantly, 25% don't understand what their medicines are for or how to take them because despite having asked, they don't feel their doctor or nurse sees the benefit of informing them.

Treatment choices:

- 60% of people with diabetes don't know as much as they would like about their treatment options, the reason given being that they don't not understand medical terms and phrases commonly used in consultations.
- 18% don't understand as much as they would like about their treatments because they can't understand what their doctor or nurse is telling them
- 36% don't know what questions to ask about their treatment options.

What happens next?

The report, presented to the Dept of Health by Adrian Sanders MP, calls upon health professionals to 'signpost' people with diabetes to the most appropriate sources of information, as well as encouraging them to ask questions. But is this enough?

Clearly the education many people have received has failed and largely for a very simple reason - lack of communication - an inability to use language that is understandable and not enough time being spent with patients. So it is hardly surprising that people don't ask questions or know what questions to ask. However, it is clear that the majority of people want more information about the medicines they take and they want to have the informed choice of treatment to which they are entitled - something that IDDT has battled for since forming in 1994.

Joanne Shaw, Chair of Ask About Medicines says:

"It's vital that people with diabetes are encouraged and empowered to ask questions, as patients who have a good knowledge of their treatment options are better equipped to make informed decisions about medicines and other treatments."

IDDT wholeheartedly agrees with this. At last we are singing from the same hymn sheet - people with diabetes should be in a position to make informed choices about their treatment. This means knowing all the options and for people using insulin, it means being informed that they do have a choice of animal, human, or analogue insulins. This applies despite Novo Nordisk's decision to discontinue their pork and some human insulins as they are not the only insulin supplier.

Correcting Misinformation!

Pork insulin will continue to be available
IDDT has been receiving many reports of people being told by health professionals that pork insulin is no longer available, especially from those who have been using Novo Nordisk pork insulin - pork Actrapid, pork Insulatard and pork Mixtard. In one case, even the GP's computer was stating that pork will no longer be available after the end of 2007.

NOT TRUE! It is ONLY Novo Nordisk pork insulins that are being discontinued, Wockhardt pork insulins will continue to be available.

- Hypurin Porcine Neutral is equivalent to Pork Actrapid
- Hypurin Porcine Isophane is equivalent to Pork Insulatard
- Hypurin Porcine 30/70 Mix is equivalent to Pork Mixtard

As IDDT was concerned at how widespread the problem could be with GP computers giving wrong information and so we followed this up. We were reassured by the Dept of Health stating that there are the four suppliers of GP Computer Systems accounting for 95% of the GP systems and they have all confirmed that Wockhardt's

Hypurin animal insulins remain on their systems as "available".

Protein

The value and effects of proteins in our diet seem to be a very neglected and yet they are essential. But did you know that they also raise blood glucose levels? Here is another enlightening article by Dr Katharine Morrison.

Protein is an essential part of a healthy diet. There are essential amino acids that the body cannot manufacture from scratch that need to be taken in to stay in good health.

For people with diabetes much fuss tends to be made about how much and what sort of carbohydrate and how much and what sort of fat you should eat, but protein seems to be given pretty short shrift.

So what sort of foods contain protein and how much should you be eating everyday?
Major sources of protein are meat, fish, eggs, cheese, nuts, soya, yoghurt, tofu and whey protein powders. Beans and legumes contain smaller amounts of protein and tend to have a lot more carbohydrate proportionately.

The American Kidney Association has minimum guidelines about the amount of protein you should be having. To calculate your minimum protein requirements, take your ideal weight in kilograms and divide by 6. The amount left gives the amount of lean protein [in ounces] in the form of meat or eggs, that you should be consuming daily. For instance a woman weighing 60kg would need 10oz of lean meat, or equivalent, a day. This would amount to 3 x 3.5 oz portions of meat daily although of course, this does not have to be consumed as meat. For example:

- a medium egg is equivalent to about one ounce of protein
- of course, a quarter pounder burger is readily identifiable as a 4oz protein meal
- a small tin of tuna is also about 3.5 ounces.

There are easy ready-reckoning methods without weighing - Dr Robert Atkins recommended that a person looks at the palm of their hand minus the fingers and attempt to match this volume 3 times daily. Another way to judge is that 3 ounces of protein is equivalent to the size of a deck of cards.

Protein has many advantages

It is one of the foods that is quickest to fill you up. Protein improves saeity [makes you feel full] and this has recently been discovered to be due to a particular chemical substance. Starting eating protein at the beginning of a meal causes the release of cholecystokinine which stimulates bile secretion.

Protein tends to take 2-4 hours to digest and still gives a rise in blood sugar, albeit a delayed rise when compared to carbohydrates. Around a third of the protein you eat will end up as blood sugar. Due to the length of time it takes for protein to appear in the blood as sugar, in someone with diabetes different insulin regimes will be required to cope with this.

For example: if a meal has a significant amount of protein such as 3-4 ounces of lean cooked meat / chicken / fish or more than 3 eggs, then a single injection of rapid-acting insulin analogue such as Humalog, NovoRapid or Apidra, will not last long enough to cover the delayed blood sugar rise from the protein eaten.

One of the easiest ways is to use regular insulin such as human Actrapid, or short-acting beef or pork insulins to cover the meal as these insulins have a duration of about 5 hours.

Achieving optimal blood sugars

Some people want to achieve optimal blood sugars and are prepared to have a more complex regime. There are two ways of dealing with the delayed rise in blood sugars after eating protein:

- an injection of rapid-acting insulin analogues before the meal to cover the carbohydrate and also give short-acting insulin such as Actrapid, or Hypurin beef or pork Neutral to cover the protein - 2 units for every playing card deck size of lean meat. The reason I say lean meat is that you don’t count the fat in the product as fat does not need insulin to metabolise it.
- people who are using only rapid-acting insulin analogues can get around the problem of delayed protein rises by giving a second, separate injection of it about an hour after the first injection. The first injection is intended to deal with the carb content of the meal and the second injection with the protein.

It is not only high protein meals that may need this approach. When there is a mixture of protein, fat and carbohydrate in a meal eg chicken korma and lasagne, these insulin-prolonging techniques can be helpful.

No substitute for self-experimentation with the guess and test method

Your meter is your best friend when it comes to figuring out “did you get it right?” and “could you be doing it differently in the future?” You are aiming for pre-meal blood sugars of less than 6, one hour after eating less than 8 and 2 hours after finishing the meal a blood sugar of 6.5 or less. For high protein meals you will need longer than 2 hours after the meal - perhaps 3 and even 4 hours after meals such as beef stroganoff and pizza.

Advantages of low carb / high protein meals

Like many other people of my age I had been on a low-fat diet since my early twenties, often feeling hungry mid-morning and yet bloated and tired after lunch. I was also pretty cranky and my nails were very soft and broke off often. I have been low-carbing for over 3 years and the difference that high protein meals have made is amazing. I eat 3 good meals a day with no need to snack in between. My energy levels throughout the entire day are excellent and my post-lunch sleepiness has gone. My irritable bowel syndrome, which I realise is mainly due to wheat intolerance, is gone. My nails are strong and I am getting colds much less frequently.

Frequent snacking can play havoc with blood sugars

Frequent snacking for people dependent on insulin can play havoc with blood sugar control, particularly if carbohydrate is taken in any quantity during these times. If extra insulin is needed to cover a snack [and this can happen with the rapid-acting insulin analogues because they are of short duration], this can lead to uncertainty about how much insulin is still left in the system before the next meal. It simply makes correction doses and meal doses much simpler to have reasonable gaps between injections.

I have certainly found that a good-sized protein meal has eliminated the need for snacking with my son Steven, and we only use extra carbs if he is having a hypo or if he is going to be undertaking particular exercise.

Meal suggestions

Meat and salad in lunchboxes and meat and vegetables for dinner are the mainstay of low carb eating. What do you do for breakfast if you are not really into bacon and eggs? Eggs have got to be one of the most versatile and commonly used breakfast items but if you get a bit sick of eggs, there are other things you can do:

- Why protein smoothies can be made up from the powders that are often sold to body builders in health food shops and these can be made up with milk or water.
- There are all kinds of soya substitute for bacon and sausages
- Low carb baking of cheesecakes, muffins, cookies and other cakes can be surprisingly high in protein when flour substitutes such as almonds, whey protein powder and soya flour are used. The use of sugar substitutes such as erythretol stevia blend, Hermesetas granular and Splenda can be used. Because cheesecakes rely on cream cheese for their texture rather than sugar, they are a particularly easy way of getting a good amount of protein into you in the morning.

Some people ask “do you never get sick of eating all that lamb/chicken/beef or pork?” I think the key to success is to vary what you are eating by using different cuts of meat, cooking methods and spices and herbs to bring out the flavour of the meat. Of course, barbecues are an absolute dream for low carbers.

I have found that certain internet sites give a hugely varied and international take on recipes that you otherwise may not think of.

Carb-Lite www.carb-lite.au.com is an excellent site that does not just have meat dishes but the whole range. Recipe Goldmine www.recipegoldmine.com and www.foodieview.com are also good sites. I hope that you will be inspired to create something a bit different from their suggestions.

Multi-Choice Questions

1. **People with Type 1 diabetes need to consider extra insulin to cover protein when the protein portion to be eaten amounts to:**

a). 1lb of meat
b). The size of a man’s palm
c). The size of a woman’s palm
d). The size of a boiled egg

2. **Three of these methods can effectively cover protein for a meal for insulin users. Which one cannot?**

a). Using a single injection of rapid insulin such as Novorapid/Novolog, Humalog or Apidra
b). Using a single injection of regular insulin such as Actrapid
c). Using 2 insulin injections of fast acting insulin separated by a length of time (split bolus technique)
d). Using an extended bolus of rapid acting insulin in a pump

3. **Ways of extending the length of time an insulin is active also helps to cover 3 of these foods. Which food does it not cover?**

a). Pizza
b). Lasagne
c). Mashed potatoes
d). Chicken korma

4. **Before you give a correction bolus you need to consider 3 of these. Which one is not a factor?**

a). Whether any previously injected insulin is active and for how long
b). Your insulin sensitivity for that time of day
c). Recent previous exercise
d). Your current weight

5. **Three of the following make food digest more slowly. Which one does not?**

a). A lot of sugar or starch in the meal
b). A lot of fat in the meal
c). A lot of protein in the meal
d). Gastroparesis

6. **In a Chinese restaurant, the best single choice would be:**

a). Crispy duck with pancakes
b). Chicken chow mein
c). Prawns, cashew nuts and assorted Chinese vegetables
d). Pork in batter with sweet and sour sauce

7. **In a French restaurant you may choose to eat any 3 of these. Which one would you not choose?**

a). Confit de canard
b). Chicken with peppercorn sauce
c). Sole meuniere
d). Crepes flamed with apple brandy

8. **In an Italian restaurant you may choose to eat any 3 of these dishes. Which one would you not choose?**

a). Risotto milanase
b). Melon with proscuitto
c). Cheese with a few grapes and apple slices
d). Steak diane

9. **In a Japanese restaurant you may choose 3 of these dishes. Which one would you not choose?**

a). Sashimi
b). Mizo soup
c). Beef teriyaki
d). Sushi

Answers
1c, 2a, 3b, 4d, 5d, 6c,

7 d - the small amount of breading on the Sole meuniere should not pose too much of a problem if you are eating non-starchy vegetables with butter and avoiding large amounts of potatoes or starchy accompaniments.

8 a - risotto is rice-based and although there can in some dishes be quite a lot of vegetables, meats and fish included, it can be a lot more trouble than it’s worth picking these out.

9 d - sushi again is very rice-based, and although you can certainly

order it and pick off the toppings which are generally very low-carb indeed, it does make it a very expensive meal. Sashimi is the straight raw fish sliced on its own.

Website Well Worth A Visit...

A new Diabetes Manual for parents of children with Type 1 diabetes from the Children's Hospital Westmead and the Royal Children's Hospital is available free on-line at:
http://www.rch.org.au/diabetesmanual/index.cfm?doc_id=2352

The same hospitals have also produced a number of DVDs and videos dealing with paediatric issues and Type 1 diabetes. These include covering toddlers, primary and secondary school, sex drugs and rock 'n roll, transition and diabetes camps. Trailers for these can be seen on line at our website:
http://www.rch.org.au/diabetes/index.cfm?doc_id=1107

Alertacall For people Who Live Alone

Many people worry about night hypos but for those who live alone, this worry is even greater as there is no one on the spot to realise that there is a problem. Families are also concerned about their relative's safety. So if you live alone, the Alertacall can check that you are up and about in the mornings and so confirm your safety and offer reassurance to you and to those who care for you. It can also be used to check that you have arrived home safely at the end of a day.

The way it works:

- You are supplied with an Alertacall telephone which is plugged into any standard working telephone socket. It is big-buttoned for people who are visually impaired and can also be used as a normal phone.
- The phone has a Special Button that you press before an agreed time each day between 8.00am and 10.00pm.
- If the Special Button is not pressed by the agreed time the 'Safety Confirmation Routine' is started. This means that the company will try telephoning you to confirm your safety. If they cannot confirm your safety [because you don't answer the phone] then they will phone up to three people who you have already chosen eg neighbours, friends or family members. If you forget to make the call, then this Safety Confimation Routine is started.

What does it cost?
There's a discount if you join through IDDT by quoting 'diabetes1' or 'iddt1'

Setup fee including Alertacall Telephone	£19.00 [normally £21.00]
Standard service [confirm safety between 8.00am and 7.00pm]	£6.50 a month [normally £8.50]
Confirm safety as late as 10.00pm	£10.75 a month [normally £12.75]

There is a money back guarantee if the Alertacall is not right for you.

Application forms can be obtained directly from IDDT, PO Box 294, Northampton NN1 4XS, tel 01604 622837 or from Alertacall, freephone 080 156 577 but remember to quote 'diabetes1' or 'iddt1'.

The Truth Hurts!

"Doctors must not be lapdogs to drug firms"
This was a warning given in the British Medical Journal by Professor

Adriane Fugh-Berman from Georgetown University, Washington DC, after she addressed an audience of physicians, nurses and other health professionals. The subject for her talk was the influence of the pharmaceutical industry on continuing medical education and as usual, pharmaceutical companies gave funds to the conference and they had exhibition stands.

In her talk Professor Fugh-Berman covered the costs of drugs, the costs of promoting drugs to doctors, the salaries of drug representatives, the funding of continuing medical education and the connection between polypharmacy and adverse drug reactions. [Polypharmacy is the prescribing of lots of drugs to one patient]. She also covered psychological profiling and monitoring of physicians, including prescription tracking.

Although the audience was very interested and aware that it was rare for this subject to be openly discussed, following her talk, several pharma companies withdrew or threatened to withdraw their support for future conferences.

Here are just some of the points that Professor Fugh-Berman makes:

- Pharmaceutical firms are not interested in presenting information important to prescribers unless it is also important to the drug industry.
- Drug representatives are paid to be nice to doctors, as long as they co-operate, sustaining market share of targeted drugs, and limiting continuing medical education lectures to messages that increase drug sales.
- The drug industry is happy to play the generous and genial uncle until physicians want to discuss subjects that are off-limits, such as the benefits of diet or exercise, or the relationship between medicine and pharmaceutical companies. Any subject with the potential to reduce drug sales is an anathema.
- If doctors remain dependent on pharmaceutical companies for sponsoring continuing medical education, then these courses will remain under the control of the drug industry. This control is not contractual, but it is enforced through psychological manipulation.

She suggests that if industry sponsorship of medical meetings is essential to conference organisers, then they could look to manufacturers of cars, luggage and travel services. Perhaps even more outrageously, she suggests that doctors could actually pay for their continuing education, as do lawyers, accountants, and many other business people.

“Medicine must shed its docility and the corporate leash,” she says. “Let us not be a lapdog to the pharmaceutical industry. Rather than sitting contentedly in our master’s lap, let us turn around and bite something tender. Freedom calls.”
BMJ Volume 333 p 1027, 10 November 2006

Did You Know?

- Patients who are admitted to A & E by ambulance three times a year or more often have one of 18 conditions such as angina, asthma and diabetes.
- Diabetes accounted for 17,686 people with diabetes admitted in emergency to hospital in a year [2003/04] on an emergency basis which cost £42 million to the NHS.

Secretary of State for Health, Patricia Hewitt suggests the way to reduce the number of emergency admissions is to have more efficient community treatment - community based nurses who look after patients at home on a regular basis, better assessment processes before admission and better communication between doctors involved in the care of a patient. Not rocket science!

From Our Own Correspondence

I'm feeling very much better

Dear Jenny,

Thanks to your IDDT website I have been on Wockhardt beef insulin for about

six weeks now. Many of my allergy symptoms with Levemir and Lantus have now

subsided. I am feeling very much better. Please sign me up and send me your literature. Frankly, your website has saved my life. I used every bit of information which you sent every few days to finally convince my doctor to write the needed 'prescription'

John
E-mail from US

Music helps with pain

Dear Jenny,

Your item in the October Newsletter suggesting that music can decrease pain and depression was interesting to me as I edit a magazine called JAZZ WEST MIDS. If any of your readers enjoy music, especially modern, mainstream or traditional, I would be happy to send them a copy of our free magazine. The other benefit is the friendship and companionship to be found at jazz clubs and festivals. Your readers can contact me on: 0121 241 6751 or e-mail jazzwestmids@yahoo.co.uk.

Keep up the wonderful work you are doing.

Linda Semp
W Mids

Hairdresser's tip

Dear Jenny,

Can I offer a small snippet of information. At IDDT's conference, a group of us were talking about hard skin on fingers where we do our blood tests. My hairdresser gave me some useful advice - rub henna wax into the skin. It feels wonderful afterwards.

Mrs C.C
Midlands

Watch the time!

Dear Jenny

Having been an insulin dependent diabetic for some 39 years, I felt I was informed enough about diabetes and the possible problems associated with it. However, I was recently proved wrong.

I have, for many years, travelled around Europe with no problem at all but this year my husband and I decided to go to New York and then to Buffalo to visit family. The problem occurred on the way home. We boarded the plane for London Heathrow at around 7.45pm and take off was delayed about an hour - not too much of a problem, it just meant my evening insulin and meal would be a bit later than usual. Dinner was served at around 9.30pm American time and after that we settled down for the night. I couldn't sleep so relaxed watching videos. However, at some stage I decided to change my watch to British time - a huge mistake because, having watched videos and perhaps nodded off here and there, we were awoken when the cabin crew served breakfast before landing at London. I looked at my watch and in a half awake state, believing it was 6am thought I should be alright to have my insulin in preparation for breakfast which was served just a few minutes later. The only thing was, it wasn't 6am American time it was only 1am - just three and a half hours after taking my evening and night time insulin!

We got off the plane, went through passport control, got our luggage and met our taxi driver to bring us home. I recall getting into the taxi but nothing after that until I came round in the A & E Department of my local hospital some time later. What a nightmare and what a fright. I couldn't believe what had happened, how or why but eventually I worked out what had gone wrong - that I had double dosed my insulin and that I should not have changed the time on my watch until we arrived back in England.

Perhaps I should have been more careful - perhaps I should have known better. But I just wanted to warn anyone considering travelling long distance to be extra careful. Above all else, don't change your clocks or watches until you land. If this warning can save just one person suffering the way the taxi driver, my husband and I suffered during that awful nightmare, then I will be happy.

Mrs S.S.
Beds

The desperation people feel when their insulin is discontinued
Dear Jenny,

Is there any way to make your own Lente out of Regular and Zinc?

Received by e-mail from the US.

* * *

Latest Report on Islet Cell Transplant

The first successful transplantations of the insulin-producing islet cells were carried out in 7 patients with Type 1 diabetes by Dr James Shapiro's team at the University of Alberta in 2000. They have since conducted a trial to assess the feasibility and reproducibility of the procedure which has concluded that the transplanted islet cells gradually lose their ability to produce insulin.

The results [New England Journal of Medicine 28.9.06] show that there were 36 adults in the trials who had Type 1 diabetes for at least 5 years with blood glucose levels that swung widely from too high to too low. Between 2001 and 2003 they all received up to 3 transplants of islet cells which were isolated from the pancreas of brain-dead donors. The main aim of the research was to achieve independence from insulin injections with adequate glucose control one year after the transplants.

After 1 year the results were:

- 16 people were totally free of insulin injections with adequate glucose control one year after the transplants
- 10 people had partial graft function with significantly improved control [still needed some insulin by injection]
- 10 people had complete graft loss - transplantation didn't work.

But after 2 years:

- only 5 people were still free of insulin injections

And after 3 years:

- only 1 person was free of insulin injections.

So the researchers concluded that the transplanted islet cells gradually lose their ability to produce insulin. A lot of has to be done before islet transplantation produces long-lasting results. Commentators have said that islet transplantation is at a crossroads as it is clear that poor long-term results, high costs, and the relatively high incidence of major and minor serious adverse events make it difficult to argue for expansion of islet transplantation to the general population. Added to this other developments such as continuous glucose monitoring devices, have the potential to change diabetes care for every patient, not just a select few. So it seems that we have to watch this space...

Finally The Decision on Inhales Insulin - No

The final NICE guidance on the use of inhaled insulin, Exubera, will not be issued until December 2006 [after our print deadline] but NICE has said that the findings of its final appraisal should be adopted. So NICE has not recommended the use of inhaled insulin for the routine treatment of people with Type1 or Type 2 diabetes. However, they allow it as an option for people with Type 1 or Type 2 diabetes who have poor control despite all other treatments being tried along with adequate educational support AND who are unable to start or use pre-meal injections because:

1. there is a marked and persistent fear of injections ie needle phobia diagnosed by a diabetes specialist or mental health professional.
2. there are severe and persistent problems with injection sites and site rotation.

Treatment with Exubera should only be continued beyond 6months if there is evidence of a sustained improvement in HbA1cs.

And In Scotland...

In September 2006 the Scottish Medicines Consortium [SMC and England's equivalent to NICE] announced that Exubera is not to be recommended for use on the NHS as manufacturers had not provided enough justification for the cost. The SMC told the press that key pieces of information were missing about the justification for the cost and they would be prepared to look at their decision again any time the manufacturers wish to make a further submission.

And In Germany...

IQWiG, Germany's equivalent of NICE, is very straightforward with its decision:

Type 1 diabetes - "According to current knowledge Exubera is not a safe alternative for patients with Type 1 diabetes to subcutaneous insulin".

Type 2 diabetes - "Published data do not provide any basis for the conclusions that Exubera is a safe alternative to subcutaneous insulin."

Interesting financial comment: a Datamonitor Report, October 2006, predicts that inhaled insulin is unlikely to achieve the blockbuster status that industry had hoped for. Their reason is that it does not alter the important issues for patients as they still have to put up with the same disadvantages of insulin treatment - hypos, blood testing, dietary restrictions, weight gain etc. Datamonitor forecasts that Exubera sales will only reach $207m by 2015, much less than the original estimate of $1.5b. Novo Nordisk, Lilly and Technoshere expect to launch their versions of inhaled insulin by 2010 so the future for these does not look very bright. Perhaps the manufacturers should have done their homework and asked people with diabetes what concerns them the most about having diabetes rather than make assumptions that it is the injections!

Have You Got a Sick Day Plan?

Winter is upon us and unfortunately this means colds, flu and loads of other bugs flying around. All of these can cause your blood sugars to rise and sometimes it rises before you even know you have an infection. In fact if they rise for no apparent reason, it can be a warning that a cold or some other bug is 'brewing'.

Your doctor or nurse should have already discussed a ‘sick day’ plan with you but here are a few golden rules:

- Insulin - don’t stop taking your insulin and/or oral medications. You may need to adjust your insulin but NEVER stop taking it.
- Blood glucose testing - test frequently and at least every 3 to 4 hours.
- Ketones - if your blood glucose levels are high [recommendation is above 13mmols/l] then you should test your urine for ketones. Vomiting can cause dehydration, high blood sugars and ketones.
- Keep hydrated - drink plenty of water as dehydration cause cause your blood sugars to rise even further.
- Eating - if you feel ill, use easy to prepare foods such as soups, cereals and juices.
- Get help - call a doctor or go to the nearest A&E Hospital Department if your blood sugars are consistently above 16mmols/l and you have signs of ketoacidosis.

And just to remind you, especially if you have Type 1 diabetes:

Ketones: Acid substances formed when body fat is used up to provide energy.

Ketoacidosis: A serious condition due lack of insulin which results in body fat being used up to provide energy and dangerous ketones and acids are also formed. It is caused by high blood sugar levels which result in ketones in the urine, vomiting, drowsiness, heavy laboured breathing and breath smelling of acetone [pear drops].

Ketonuria: The presence of acetone and other ketones in the urine. Detected by testing with a special testing stick or tablets. Ketones in the urine are due to lack of insulin or periods of starvation.

Dry Eyes and Diabetes

Dry eye is a very common condition that affects many people over 45, especially postmenopausal women. However, people with diabetes have a significantly increased risk of dry eyes.

Symptoms: gritty, sandy feeling in the eyes, burning, itchy, blurring vision and light sensitivity, redness and oddly, increased watering of the eyes. It usually affects both eyes.

Causes: tears consist of three layers - an outer oil layer that prevents evaporation of the tears from the surface of the eye, a watery middle layer and an inner mucus layer that allows the middle watery layer to adhere to the surface of the eye. A shortage or abnormality of any of these layers results in the symptoms of dry eyes but the most common cause is insufficient quantity of the water layer produced by the tear [lachrymal] glands under the upper rim of the eye socket.

Causes in people with diabetes: research suggests that dry eyes in people with diabetes is caused by insufficient production of tears due to autonomic neuropathy affecting the nerves that control the lachrymal glands. Autonomic neuropathy is nerve damage that affects the involuntary nerves.

When the front surface of the eye [the cornea] is no longer sufficiently lubricated the cells of the cornea become damaged and free nerve endings are exposed, leading to dry eye symptoms. If the nerves of the cornea are severely damaged, then there may be relatively few symptoms and this is dangerous as the pain is a warning that something is wrong.

Treatment: keeping blood glucose levels as tightly controlled as possible is the first step in both prevention and treatment of dry eyes but there are various medical treatments. Theses include artificial tears, medications to increase tear production by the lachrymal glands or blockage of the tear ducts to prevent the tears draining away through the nose. It has also been shown that increasing the amount of omega 3 fatty acids [oily fish] in the diet can increase the quantity and quality of tears.

By the way - new drug for retinopathy is not approved

In previous Newsletters we have reported that drug company, Eli Lilly have issued statements implying that they expected their new drug to treat retinopathy to receive approval shortly, giving hope to people with diabetes. But in September 2006 the US drug regulator, the FDA, called for further 3 year trials before it will consider approving the drug, ruboxistaurin mesylate, for treatment of moderate to severe retinopathy. Lilly has said that it will take 5years to complete these trials, so they are 'evaluating their options' for the further development of the drug.

Cochrane Review of Type 2 Drug - Actos

Actos, [pioglitazone] is a drug treatment used for Type 2 diabetes and belongs to the glitazone family of drugs. They work by increasing the body's sensitivity to insulin. NICE recommends that glitazones are only used when other, older drugs are not effectively lowering blood glucose levels. There has now been a Cochrane Review of clinical trials published on 18th October 2006 in the Cochrane Library, www.cochrane.org

After evaluating clinical trials of 24 weeks or longer in which patients were treated with Actos, the Cochrane Review concluded that there was 'no convincing' evidence that the drug reduced mortality, morbidity or adverse effects, or improved health-related quality of life. In addition, Actos did not seem to improve metabolic control compared to other drugs for type 2 diabetes but on the contrary, it was more commonly associated with fluid retention than were other drugs.

Results from the United Kingdom Prospective Diabetes Study (UKPDS) and the University Group Diabetes Program (UGDP), the two biggest type 2 diabetes trials, also failed to show that the adverse effects of cardiovascular disease were lessened by improved metabolic control in diabetic patients.

Dr Bernd Richter of the Cochrane Group concluded that "Pioglitazone treatment should be restricted to patients demonstrating real benefit of this therapy. Patient benefits should not be postulated on the basis of improvement of metabolic parameters...alone but should refer to patient-oriented outcomes such as fewer diabetic complications or better health-related quality of life."

Note: People with Type 2 diabetes are 2 or 3 times the risk of stroke than the general population and people who have already had one stroke are at a greatly increased risk of further stroke. Recent research has shown that in people with Type 2 diabetes who have already had one stroke, the risk of further strokes is halved in those treated with Actos.

More on the Reliability of HbA1cs

The HbA1c test is used as a measure of average blood glucose control over the previous 6 to 8 weeks and clinics use it as an indication of diabetes control. It measures the glucose attached to the red blood cells and these cells live for about 90 to 120days. So it measures high sugars but cannot measure lows ie hypos. Some time ago we reported that the HbA1c test is not infallible. The results can be classed as 'good' [7% or under] when actually the reason is that the person has had lots of hypos which of course, is not good diabetes control! In addition to this, research has shown that HbA1cs tests can give differing results according to the time of year - higher in winter.

In September the British Medical Journal reported two cases emphasising that the HbA1c is not infallible. The first was a 60year old lady with Type 2 who developed complications despite having an HbA1c of 7%. Further investigation revealed that her home blood glucose results were regularly high - between 12 and 21 mmol/l and it appeared that she had an increased turnover of red blood cells ie hers did not live the normal 120days so giving false low HbA1cs. The second case was the opposite -a 57 year old man had an HbA1c of 9.7% and fasting blood glucose of 14.8 mmol/l. He was treated with metformin, then a sulfonylurea was added and this reduced his HbA1c to 8.7%. After a collapse at work, further investigations showed that his home blood glucose test results were between 2.4 and 6.8 mmol/l.

The report stated that both these cases gave misleading result because the lifespan of the red blood cells was different from the average eg if blood loss through some cause is sufficient to shorten the average lifespan of the red cells to 90days, the HbA1c results could theoretically be halved. The report concludes that while the HbA1c levels are a convenient way of measuring blood glucose control, they might not be appropriate for everyone.

Reynolds, T. Smellie, W. et al. 2006, ‘Glycated haemoglobin (HbA1c) monitoring’, BMJ, vol. 333, pp. 586-588.

Aggressive Disbetes Treatment Can Be Stressful

Recent research carried out in the Netherlands [Diabetes Care, Oct 2006] has shown that when people are identified as having Type 2 diabetes a result of screening, they usually experience little anxiety in the first years after the diagnosis. However, the research shows that early and intensive treatment appears to lead to higher anxiety and less ability to cope.

The article states that there is an ongoing debate on screening for type 2 diabetes with one side emphasising the advantages of detecting diabetes at an early stage of the disease because early and intensive management may reduce diabetes-related illness and death. But opponents to this view say while the psychological consequences of early detection and treatment are unclear that this approach is not certain.

The researchers studied 196 patients diagnosed with diabetes 3 to 33 months previously who were receiving usual care or intensive treatment. The majority of patients reported little distress and low levels of perceived seriousness and vulnerability, and felt confident coping with the disease but those who received intensive treatment reported more distress and less self-confidence in the first year.

The authors conclude that the study:

- emphasises the importance of taking variations between patients into account in the development and implementation of self care programmes for patients with a recent diagnosis of type 2 diabetes during a screening trial.
- that doctors should be more attuned to patients’ psychological needs when they first prescribe intensive treatments.

Should we ask similar questions about the treatment for Type 1 diabetes?

Let’s just take a look back to only a few years ago. Originally ‘intensive treatment’ meant multi-daily doses of insulin with the aim of achieving normal blood sugars and ‘usual care’ often meant twice daily injections with people doing their best to achieve blood sugars as near normal as possible. It was recognised that ‘intensive treatment’ involved more daily injections, more daily blood glucose testing, better education and of course, a greater risk of more episodes of severe hypoglycaemia and weight increase. Most importantly, it was recognised that this regime was not suitable for everyone, not everyone wanted or could manage a complex regime.

But what have we got now? An increasing use of insulin analogues and a likelihood that in future there will only be insulins analogues. And this means that people with Type 1 diabetes and many with Type 2, will HAVE to use a regime of at least 4 injections a day - in other words, intensive treatment! Yet the above research showed that people on intensive treatment reported more distress and less self-confidence! So the increasing use of analogues requires a more complex way of managing blood sugars which could well increase number of people with low self-esteem, anxiety and stress. Even if doctors are attuned to patients' psychological needs, the reduction in types of insulin reduces their options to help patients.

Yes, there are pre-mixed analogue insulins that may be OK given twice daily, but we all know that they remove flexibility of dose and injection timing. Twice daily injections of separate short- and longer-acting animal or human insulins can still be geared to suit the activities and meals and for some people are a much easier to manage blood sugars. Do we really want to be left with little choice of insulin and the resulting effect of complicated regimes that reduce the quality of life of some people?

Good Thought!

Generally speaking, you aren't learning much when your lips are moving.

Thanks From Dream Trust

As regular readers know, Dream Trust is a clinic for children and young people in Nagpur, India founded and run by Dr Sharad Pendsey and his team. The support of our members and friends in sponsoring children, making donations and donating unwanted insulin is very much appreciated by everyone at Dream Trust, especially the children and young people. Dr Pendsey has asked IDDT to thank all the donors who are helping these vulnerable children and young people.
Thank you!

Apologies For Error

Sorry about the error in the October 2006 Newsletter to 'Test Your Knowledge'. The answers should have been: 1 [c], 2 [d], 3 [c], 4 [a], 5 [a], 6 [c], 7 [d], 8 [a].

Date For Your Diary

IDDT's Annual Conference for this year is Saturday, October 13th 2007 and it will be in Birmingham.

Snippets...

Guess what - Aspartame is a great ant-killer!
As we have discussed several times, the sweetener, Aspartame, has dire adverse reactions in some people with a great long list of adverse effects. A lady in the US had fire ants [imperviouse to many poisons so, knowing the toxic properties of aspartame, she emptied a packet in each corner of her bathroom. The ants ignored it until it was moistened with a little water, then they came back with a vengeance and took the aspartame back to their nest. Within two days the ants had disappeared and have not been seen for the last 2 years! It's not a mystery really as aspartame works like a pesticide as it contains asparctic acid which is toxic in large enough quantities. [Idaho Observer June 2006]

Wearing a helmet for cycling, not as safe as you might think!
Research has shown that car drivers pass closer to cyclists wearing helmets than they do people without helmets. As a result helmets

could indirectly increase the risk of collision and therefore injury. A traffic psychologist in the US fitted a cycle with a computer and an ultrasonic distance sensor and recorded distance information from over 2,500 passing cars half the time wearing a helmet and half not. He found that drivers were twice as likely to get close to the cycle while he was wearing a helmet an on average passed 3 inches closer than when he wasn't. [EurekaAlert 11.9.06]

Trials go wrong and research boss receives £920,000 bonus - the four men who almost died after the Parexel Laboratory trials went wrong have so far been given £10,000 for immediate medical expenses and no compensation. However, the chairman of Parexel received a bonus amounting to £920,000 in cash and share options giving him an overall package salary of £1.16million in the same year. The lawyer acting for the men said that they were 'outraged and incensed' especially as the company are refusing to discuss compensation. A report by the Medicines and Healthcare products Regulatory Agency, the Government's drug watchdog, said Parexel had failed to follow several procedures [BBC 5.11.06] but the watchdog itself has also been criticised.

US health system did not come out well!

A new study released by the Commonwealth Fund's Commission on a High Performance Health System shows that the US health care system is fragmented, wasteful and in some cases dangerous, and is particularly poor at serving the very young and the very old. The US spends more on health care than any other country but has the highest infant mortality rate of nearly two dozen industrialised nations, and the lowest life expectancy after 60. The study suggested that improvements in the health care system could lead to saving 150,000 lives and $100 billion annually. Currently, one-third of patients report a medical, medication or lab test mistake, and a quarter of American adults have had to wait at least six days when they needed medical attention.

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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