



## 20 Years of Independence

Welcome to our first Newsletter of 2014 and our new look!

IDDT published its first Newsletter in April 1994, so this Newsletter is special as it celebrates our achievements over the 20 years since our formation. '20 Years of Independence' is an achievement in itself. It is 20 years without accepting pharmaceutical industry or other funding which could be seen as biasing our position and the information we provide to you. There are times when this has been, and still is, a real financial struggle, but our reputation and reliability rests on our independence.

In 1994 we had just a handful of members but by the beginning of 2014, we have over 30,000 members, not something we expected. Our membership consists of people with Type 1 and Type 2 diabetes and their families, parents of children with diabetes and healthcare professionals who are so important to the health and wellbeing of us all.

As regular readers are aware, the reason IDDT formed was to maintain supplies of natural animal insulins for people who have adverse effects when using synthetic GM, so-called 'human' insulin. Our first big break came in the Autumn of 1994 when Newsnight on BBC2 broadcast the reasons for the formation of IDDT and the problems some people experienced when using synthetic 'human' insulin. Newsnight also made public the adverse reaction reports from the then Committee on the Safety of Medicines - the Yellow Card Scheme which still operates today.

- Human insulin reports from 1982 to 1994 showed 13 deaths that could be linked to human insulin were reported and 385 reported adverse reactions.
- Animal insulin reports 1963 to 1994, a much longer period, which showed 2 deaths that could be linked to animal insulin and only 38 reported adverse reactions.

Despite the late hour of the programme, IDDT's phone started ringing immediately after, so we knew that our cause was justified.

Our members lobbied and wrote hundreds of letters over the years in their determination and desperation to maintain the

animal insulin they needed and 20 years later, animal insulins are still available. However, we must also recognise the doctors who courageously spoke out and put their reputations on the line to ensure that animal insulin remained available. So a huge thank you goes to the late Professor Arthur Teuscher, Dr Matthew Kiln and Dr Laurence Gerlis without whom animal insulins would have disappeared many years ago.

For this new look 'celebration' issue, we are including a pull-out copy of our very first Newsletter to show how IDDT has developed over the years. Also included are our key achievements and articles from the last 20 years, not just to blow our own trumpet, but to demonstrate that determination, accurate facts and empowerment of people with diabetes can be successful. These are lessons worth remembering in these changing times for health care and the NHS.

### In this issue ...

- Sharing your health records
- Action Diabetes
- A bit of IDDT history
- Debates – aspartame, statins and aspirin
- Research News

## Just a note...

**Your next mailing from us in June will be back to usual – the Newsletter, Type 2 & You and the Parents Bulletin. This is a one-off special which looks at both the past and the future. It demonstrates how IDDT has developed and grown over the years. This is thanks to you, our loyal and growing membership. So thank you! We hope you enjoy this special 20 year celebration Newsletter.**

# Sharing Your Health Records

NHS England has commissioned the Health & Social Care Information Centre (HSCIC) to collect patient information from all providers of NHS care on a monthly basis.

Leaflets began to arrive at all 22 million households in England during January as part of a campaign by NHS England to tell people about its plans to extract and share information from their medical records. It is called the care.data programme. The mailing alone is costing £2million and runs alongside local data collection by Clinical Commissioning Groups [CCGs] and other organisations.

NHS England believes that this information from patient records can provide 'NHS organisations, citizens and researchers with accurate, timely information which will radically transform the way we care for and treat people and continuously improve the services we offer.'

## How will you receive your NHS England leaflet?

At the time of writing only one member of IDDT's staff had knowingly received his leaflet and why do we say 'knowingly'? He happened to find it in the load of junk mail through his letter box advertising pizza delivery, supermarket offers etc. The rest of us may have received it but most of us don't look in the piles of junk mail, we simply bin the lot and how many other households will do the same.

The importance of this is that if you don't want your information shared you have to **opt out by letter to your GP** but if you have accidentally thrown away the leaflet or you ignore it, then your personal, confidential information will automatically be shared. This, of course, is the advantage of an opt out system, people actually end up opting in out of default rather than making an active decision to opt in!

Interestingly, one of IDDT's Trustees who visited her GP received the following note.

## To all patients

**Urgent – do not ignore this information – if you are not happy for confidential information about you to be shared then you need to advise us, otherwise you will be deemed to consent.**

**If in doubt we recommend you "opt out" – act now!**

## What information will be taken from patient records?

- NHS number
- Date of birth
- Postcode
- Gender
- Coded information about referrals
- NHS Prescriptions
- Other clinical data

So this begs the question, surely this information will make patients personally identifiable?

## Medical research charities launch 'Sharing data saves lives' campaign

In mid-January to coincide with NHS England's mailing, some leading medical research charities, including Diabetes UK, Arthritis Research UK, Cancer Research UK, the British Heart Foundation and the Wellcome Trust, launched an advertising campaign to raise awareness of the importance of sharing information from patients records with researchers. The researchers can be from universities and from pharmaceutical industry. Yes, this information is undoubtedly useful for research. The campaign says this will be non-identifiable information and you can opt out – but read on...

## What is the real position?

- NHS England has been given legal exemptions to pass identifiable data gathered by the HSCIC between itself and a range of regional processing centres, local area teams and commissioning bodies that came into force on April 1st 2013.
- HSCIC also provides access to patient information, some in identifiable form to a range of 'customers' including private companies. Are these 'customers' going to pay for our information?
- Potential users and wide range of users are not yet defined and therefore cannot be regarded as secure.
- No guarantees can be given about future re-identification or future changing the identification information and the HSCIC has admitted this is a risk.

## What do I do next?

**If you are happy to share** your private and confidential GP records, you need do nothing as this is implied consent.

**If you do not want to share** you have to write a letter to your GP and as a minimum you must say:

- Please take whatever steps are necessary to ensure that my personal, confidential information is not uploaded and record my dissent by whatever means possible.
- This includes adding 'Dissent from secondary use of GP patient identifiable' to my record as well as 'Dissent from disclosure of personal, confidential information by HSCIC'.
- Please ensure that any of my information used for these purposes is treated in this way and that other providers are made aware of my wishes
- You should include your name, address, date of birth and NHS number, if known.

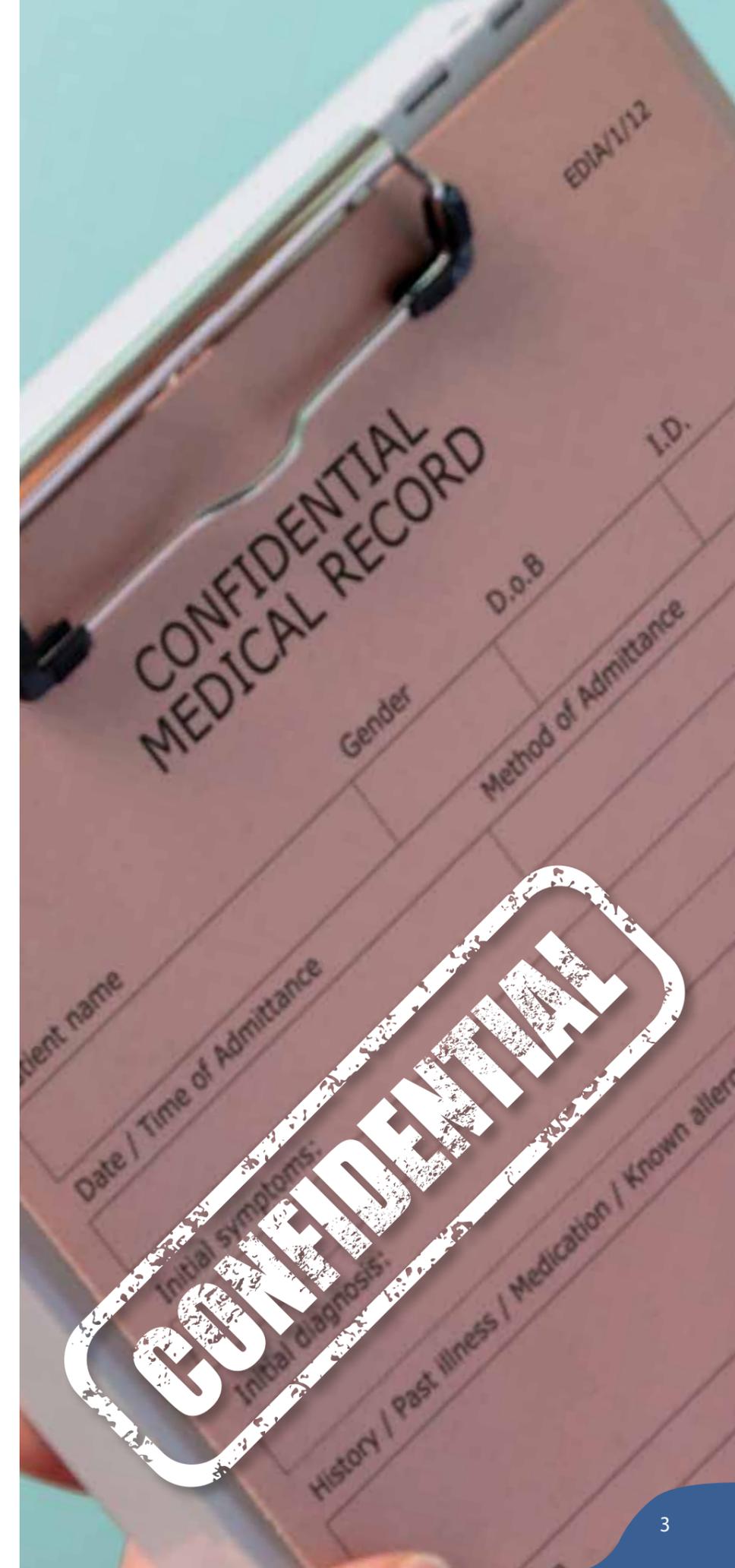
If you have access to the internet, there are two websites that have the letter already written for you and all you need to do is fill in your details and send it off to your doctor. These are:

<http://medconfidential.org/how-to-opt-out/>

[www.medconfidential.org/wp-content/uploads/2013/08/opt\\_out\\_letter.pdf](http://www.medconfidential.org/wp-content/uploads/2013/08/opt_out_letter.pdf)

The original closing date for opting out was January 31st 2014 but the 'junk-mail' leaflet does not have a date and also says that you can change your mind at any time. So if you want to opt out, just send the letter to your GP.

**Latest News: just before going to print, it was announced that due to pressure, the date for this has been delayed until August 2014.**



# IDDT Anniversary Conference – a date for your diary

## '20 Years of Independence'



This special anniversary conference will take place on Saturday, October 18th 2014 at the Kettering Park Hotel, Kettering. If you are wondering where on earth Kettering is, it is just off the A14, so easily accessible from north, south, east and west by car and an hour's journey from London by train.

We have Dr Charles Fox, Dr Laurence Gerlis, Dr Gary Adams as confirmed speakers and discussion groups run by Diabetes Specialist Nurses from Kings Lynn

We hope many of you will be able to join us to learn more about diabetes, meet other people who live with diabetes and above all, have an enjoyable day out. We will be sending out the programme and application forms with the June Newsletter but for now, make a date in your diary – October 18th 2014.

## Midlands Diabetes Study Day for Healthcare Professionals

This is the second in a series of Diabetes Study Days run by IDDT for healthcare professionals, which will take place on Friday, May 16th 2014.

The venue is the Paragon Hotel, Birmingham which has a car park and is 10 minutes from the railway station. The benefits are:

- Refresh your diabetes knowledge
- Learn about new developments
- Share good practice
- Pick up CPD points.

The programme and application form is included with this newsletter but you can register on line at [events@iddtinternational.org](mailto:events@iddtinternational.org) or call IDDT on **01604 622837**.

# Action for Diabetes' – NHS England

The National Diabetes Audit [October 2013] of care and treatment of people with diabetes showed lack of improvement and very significant numbers of people still not receiving the NICE health checks. Here are some examples.

## Blood pressure targets not being met in half of the country

1.2 million people with diabetes in England and Wales did not meet the target blood pressure of less than 140/80. Blood pressure targets are important to reduce the risk of stroke and heart attacks. Most people with Type 2 diabetes have high blood pressure.

- Half the clinical commissioning groups [CCGs] and local health boards [LHBs] did not meet the blood pressure targets. Some CCGs and LHBs were able to meet targets in 53% of cases but others only managed less than 44%.
- For all people with diabetes blood pressure targets were met in only 48% of cases.

## No improvement in the numbers of health checks

While the Audit showed a slight improvement on last year in the numbers receiving the necessary health checks, this was not sufficient to ensure a real reduction in the complications of diabetes.

- 58% of people with Type 1 diabetes did not receive all the relevant health checks.
- Younger people were less likely to receive all the checks.
- In some areas as many as 75% of people received the checks but in others it was much lower.

## Only 1 in 10 people newly diagnosed people with diabetes are offered education

The Audit showed that only 13.5% of people newly diagnosed with diabetes were recorded

as being offered a structured education course during 2011/12 and less than 1 in 30 [2.9%] were recorded as actually attending a course.

The situation is worse for people with Type 1 diabetes – only 2.7% of people newly diagnosed with Type 1 were recorded as having been offered structured education and just 0.6% as having attended a course. These figures are particularly bad because NICE recommends that everyone with diabetes should be offered a structured education course.

## Action of the Public Accounts Committee

A report by the Public Accounts Committee on adult diabetes services [2012] highlighted that the care of people with diabetes had not really improved and that there is great variation in services across the country – some good and some not good. As a result, a new document was published in January 2014 called 'Action for Diabetes' by NHS England. This document was prepared by Domain 2 – Long term Conditions, Medical Directorate, the new NHS body responsible for diabetes.

## Who is the document for?

The document has been circulated to everyone involved in providing services to people with diabetes, so they all know what is required of them. It says that it is *'for Clinical Commissioning Groups [CCGs] as a reference on the work that is going on across NHS England, and for the wider community interested in diabetes care to see what action NHS England is taking in this important area.'*

## What does the document say?

The 30 page document describes the action NHS England is taking now and in the future and the aim is to:

- Drive the prevention of Type 2 diabetes and earlier diagnosis of all diabetes.
- Support better management of diabetes in primary care.
- NHS England will provide leadership and support to CCGs to deliver high quality care as set out by NICE.

However, there is a marked lack of detail of how or when this will be achieved.

## Then there's 'The House of Care'

We had the 'Year of Care', now have the 'House of Care'! There are diagrams of Houses of Care for national, local and personal levels to support:

- Information continuity – where people, carers and professionals will have the right information needed to provide the right care at the right time.

- Management continuity – where care and support along recommended pathways will be available as and when needed by people.
- Relational continuity – where people will know where and who to turn to for assistance in managing their conditions.

## How will quality in outcomes for people with diabetes be assured?

For patients, this is probably the most valuable part of the document as it tells us that CCGs and NHS England have a statutory duty to improve quality of services and that they are accountable for meeting this duty.

- NHS England is held to account for improving outcomes by the Secretary of State and is responsible for ensuring that CCGs meet this statutory duty.
- Where CCGs are found to be at risk of failing to deliver improvements, NHS England firstly will support CCGs to make the required improvements and statutory intervention powers will be the last resort.

In ordinary language this means that if your CCG fails to improve services, NHS England will help them and if improvements are still not made, the Secretary of State will take action against the CCG.

## What does this mean for us?

We could have hoped that 'Action for Diabetes' would have some interesting facts about actual improvements for patients but once again, it is a document largely about processes, not about people. It is lacking in detail. It uses jargon, such as 'delivery dashboard'! It tells us what NHS England is planning and what it will do in the future. It is about hopes that there will be improvements but we want to see detailed action plans not hopes.

Yet again it means that as patients we have to be vigilant, we have to ensure that the checks we should expect as recommended by NICE, are actually carried. For this we have to be aware of the care we should expect to receive.

This information is in IDDT's leaflet 'Diabetes - Know Your Rights' and if you would like a copy, call IDDT on **01604 622837**, email [enquiries@iddtinternational.org](mailto:enquiries@iddtinternational.org) or visit our website [www.iddt.org/publications/leaflets](http://www.iddt.org/publications/leaflets)

# NICE – long-term conditions in minority ethnic groups

NICE's local government range of public health briefings aim to help local authorities with their new role of improving the health of their communities.

Using body mass index [BMI] to help prevent long-term conditions in minority ethnic groups is one of the latest topics for local authorities from NICE.

People from black, Asian and other minority ethnic groups are up to 6 times more likely to be diagnosed with Type 2 diabetes or stroke, and 50% more likely to die from cardiovascular disease than people in the wider population. To reduce the risks of these diseases, NICE has introduced new thresholds for ethnic minority groups:

- 23 kg/m<sup>2</sup> BMI or more as the threshold for increased risk of chronic conditions
- 27.5 kg/m<sup>2</sup> BMI or more for high risk of chronic conditions
- usual thresholds of 25 kg/m<sup>2</sup> and 30 kg/m<sup>2</sup> are recommended for white European adults.

## We Need Your Help!

Have You Experienced A "Lack Of A Hypoglycaemic Warning"?

If so, please contact:  
Dr Gary Adams  
Insulin and Diabetes Experimental Research Group  
Faculty of Medicine and Health Science  
University of Nottingham  
Clifton Boulevard, Nottingham NG7 2RD  
Or email Gary at Gary.Adams@nottingham.ac.uk

# NHS NEWS

## Telehealth abandoned

Plans set out 2 years ago by ministers for 100,000 patients to benefit from telehealth in 2013 [and 3 million by 2017] have been scrapped after progress stalled in the middle of 2013. In November last year Health Secretary Jeremy Hunt said that 100,000 patients in 7 areas would benefit from telehealth in 2013 but an investigation by GPonline found that only 2,368 patients were actively using telehealth. NHS England has taken over the programme and has radically overhauled it. It is still expected that 3 million people will benefit by 2017. Perhaps we shouldn't hold our breath!

## NHS electronic feedback

The NHS in England is launching a review website to allow patients to post feedback and complaints on line. The website, called Care Connect, has been trialled in 20 hospitals in London and the northeast and will be rolled out nationally during 2014. So keep so keep your eye out for this.

## Healthcare professionals to apologise for 'care failings'

The Health Secretary, Jeremy Hunt, has called for health professionals to be more "open and honest" when things go wrong in order to win back patient trust in the NHS. Guidance has been sent to every hospital in England and Wales which makes it clear that "saying sorry is the right thing to do" whenever there has been a failure of care. The NHS Litigation Authority has clarified that saying sorry is not an admission of legal liability. [January 2014]

## Health and care being delivered closer together [4.11.13]

Care and Support Minister, Norman Lamb, announced 14 initiatives to make health and social care services work together to provide better support at home and earlier treatment in the community. The aim is to prevent people needing emergency care in hospital or care homes.

In areas where these initiatives have been tried the results showed:

- 2,000 fewer patient admissions over a two and a half year period, achieved through teams of nurses, social workers, occupational therapists and physiotherapists working together to prevent crises,
- waiting times reduced from 8 weeks to 48 hours for physiotherapy services by professionals working closer together,

- setting up a crisis house where people who with mental health problems can get intensive support.



One of the reasons for these initiatives is that the number of people with more than one long-term condition such as diabetes, asthma or dementia is set to rise from 1.9 million in 2008 to 2.9 million by 2018. It is hoped that delivering better joined-up care will decrease the pressures on A&E department.

## NHS England urges patient to 'self-care'

A new campaign 'The Earlier, The Better' was launched by NHS England in January. It advises patients not to store up problems but to seek advice earlier. It is targeting people over 60 years old, carers and those with long-term conditions. The campaign aims to reduce, unnecessary stays in hospital and comes as a result of the urgent and emergency care review [November 2013] which highlighted the increasing number of avoidable emergency hospital admissions.

There will be posters on billboards, bus stops, shopping centres, supermarkets and near to pharmacies in addition to newspapers, magazines, radio and websites.

According to NHS England, urgent access to medication, primary and community care is key to reducing avoidable hospital admissions for frail elderly people and those with long-term conditions. It also reduces pressure on NHS services.

So what actions does NHS England expect us to take that we are not already taking? We will have to wait for the billboards but so far we have been told that if a patient feels they need access to NHS services, then they should do so. According to the campaign, often people can safely treat their own minor conditions or ailments by visiting their pharmacist for non-prescription medication.

According to Dr Maureen Baker, Chair of the Royal College of GPs, there are numerous benefits for patients from self-care as long as they are supported by their GP.

- Patients are in control.
- They can improve the quality of their lives.
- It can dramatically improve their physical and mental health and wellbeing.



# A bit of IDDT history from our Newsletters

## January 1995, Issue 3, Hitting the Brick Wall

IDDT's early lobbying resulted in a letter from the then Secretary of State for Health, Virginia Bottomly, who stated that the safety of 'human' and animal insulin is comparable but "I cannot agree that the use of animal insulin is a necessity although I continue to support both types." This is when IDDT first felt to be hitting a brick wall.

## July 1995, Issue 5, the Needs of Parents

IDDT was increasingly contacted by parents of children of children with Type 1 diabetes, so part of the quarterly Newsletter started to be devoted to the needs of parents. The initial article discussed the feelings experienced by parents when their child is diagnosed – shock, denial, anger, guilt, sadness and grief.

## October 1995, Issue 6, Correction of the misinformation

IDDT issued a press release to contradict widespread misinformation that IDDT wanted 'human' insulin to be totally removed from the market. IDDT has always said that 'human' insulin suits many people but not everyone, so the choice of animal insulin must remain available.

## January 1996, Issue 7, British National Formulary, a major breakthrough

The British National Formulary, September 1995, provided a major breakthrough by stating, "*Preparations of human sequence insulin should theoretically be less immunogenic, but in trials no real advantage has been shown.....some patients have reported loss of warnings of hypoglycaemia after transfer to human insulin. Patients should be warned of this possibility and if they believe that human insulin is responsible for their loss of warnings it is reasonable to transfer them back to porcine insulin..... Indicators for changing from animal to human preparations must be carefully considered in the light of these reported problems. A very small number of patients have*

*died in bed without a known cause.*

*There is no evidence that human insulin was responsible and the cause is still under investigation."*

## April 1996, Issue 8, the needs of family carers

This issue highlighted that family carers of people with diabetes, especially those with deteriorating health, can experience stress, fatigue, depression, worries about hypos and about the future. It is important to recognise the special and different needs of carers so that they receive help and support.

## July 1997, Issue 13, Animal Insulin in pens!

On April 8th 1997, C P Pharmaceuticals [now Wockhardt UK] launched an extension of their animal insulin range to produce animal insulins in cartridges for use with injection pens. The major insulin manufacturers did not produce animal insulin in cartridges for pens, so people who wanted to use pens had to use synthetic 'human' insulin. So for the first time, the 50,000 people in the UK who needed natural animal insulin had the choice of using a pen.

## October 1999, Issue 22, the formation of IDDT- International

IDDT-International was launched to join together groups from around the world all of whom were fighting for the continued availability of animal insulin. From the outset IDDT had always believed that the adverse reactions to 'human' insulin could not be happening just in the UK and Switzerland, as was so often said by the manufacturers and others.

## April 2000, Issue 24, the good and the bad news

**Good news** - pens and pen needles became free on the NHS from March 2000. **Bad news** - Novo Nordisk made a statement on February 7th 2000 that pork insulin was to be removed from the US and the company intended to remove pork insulin from the world market by the second half of the decade. IDDT issued its strongest message to date. We publicly declared that we had hoped that logic, common sense, reasoned argument and even appeals might be effective in

ensuring the needs of so many people requiring animal insulin, would not go unanswered. However, we were wrong and vowed to fight for the survival of animal insulin and the people who need it, regardless of where they live.

## July 2002, Issue 33, Collecting unwanted insulin

IDDT published the results of IDDT's first year's collection of unwanted, in-date, insulin to send to developing countries. We are the UK arm of 'Insulin for Life' to help people who cannot afford the insulin they need.

## October 2002, Issue 34, Sponsoring a child in India

IDDT launched 'Sponsor a Child' to help children at Dream Trust in India where poor families have difficulty affording insulin for their children with Type 1 diabetes to stay alive. The sponsored children are given free insulin, their medical care and vocational training to help them obtain employment, which is especially important for girls with diabetes whose parents find it difficult to arrange marriages.

## January 2003, Issue 35 Novo Nordisk had a change of heart!

*"After careful consideration and acknowledging that approximately 20,000 patients are using our animal insulin, it has been decided to continue to supply Novo Nordisk animal insulin products to the NHS." So IDDT's battles had some effect.....*

## January 2005, Issue 43, a huge step forward by a Minister

The lobbying of MPs resulted in an Adjournment Debate on diabetes led by David Amess MP who presented an excellent case for continued availability of animal insulin. The then Parliamentary Under-Secretary of State for Health, Dr Stephen Ladyman responded, "*..... to the best of our knowledge there are no plans to discontinue the production of the two types of insulin. Were we to become aware of such plans, we would of course, express a view and our clear view is that which type of insulin a patient receives should be a clinical decision.*

*That decision certainly should not be controlled by commercial considerations or issues of availability."*

This was a huge step forward as the Department of Health had always maintained that it could not interfere with commercial decisions.

## October 2005, Issue 46

This was one of the most important Newsletters we published – it was the culmination of 11 years hard work by IDDT and its members. On July 11th 2005, we had a meeting with the then Minister of State for Health, the Rt Hon Jane Kennedy MP and Department of Health officials. As a result of this meeting, IDDT received a long letter from the Minister and the key statements were: "*The Department of Health fully accepts that some people are better suited to animal insulin and that animal insulin must continue to be available. There is no overwhelming evidence to prefer one species of insulin over another and patients should not be changed from one species to another without reason.*"

In addition, she also stated that the profile of the animal versus human insulin needed to be raised, particularly with doctors. "*I have asked officials to make arrangements for another article to appear in 'Current Problems in Pharmacovigilance' and to liaise with the National Diabetes Support Team on the possibility of including an article on the Yellow Cards Scheme in its next briefing.*"

In the light of these statements, the UK government had no alternative but to make provisions for the ongoing supply of animal insulins. Failing to do so would make the government responsible for the consequences – the decline in health and possible death of people unable to tolerate GM insulins. By making choice available to suit all needs, the government passed responsibility to where it belongs – with the prescribers, hopefully in discussion with patients.

Here is just one of the many letters that IDDT received.

- It is not often that my mail produces tears of joy, but this was the effect of your letter. Thank you for all your hard work so far. The results that you have produced are fantastic. Now I am going to write to my MP and thank him.

## January 2007, Issue 51 After 15 years, pork insulin returned to Australia!

Novo Nordisk removed pork insulin from Australia in 1991 and those people who needed it had to import it from the UK at high cost and risk of it being damaged due to the high temperatures. In 2007, Aspen Pharmaceuticals reached an agreement with Wockhardt UK. Aspen agreed to keep stocks of pork insulin in Australia and supply to people through the Special Access Programme and at a much lower price than importing from the UK.

## April 2008, Issue 56, Novo Nordisk break their promise

At the end of 2007 and despite earlier promises, Novo Nordisk discontinued their pork insulin in the UK. Across the country, some doctors, health professionals and pharmacists told their patients that animal insulins were no longer available so they would have to change to analogue insulin. Of course, this was not true as Wockhardt UK supplies both beef and pork insulin. IDDT was inundated with calls from people desperate to know how to get hold of animal insulin. We vowed to continue our advertising campaign through local newspapers to inform people with diabetes that animal insulins continue to be available. A plus in all this was that IDDT's membership grew significantly!

## January 2011, Issue 67, Human Mixtard 30 gone!

Unsurprisingly, Novo Nordisk, the manufacturers of Human Mixtard 30, ignored the needs and wishes of patients, doctors, health professionals and the NHS and removed Human Mixtard 30 insulin from the market for 'commercial reasons'. This insulin was used by over 90,000 people with diabetes. IDDT joined the battle to try to prevent this discontinuation and signed the online petition on which one GP wrote, "I hope that Novo Nordisk will reconsider its decision to discontinue Mixtard 30. I won't forget if it will not."

## October 2011, Issue 70, the launch of 'Diabetes – Everyday Eating'

The most frequent help people request from IDDT is about their diet especially those with Type 2 diabetes. Then one gentleman said "I want to be told what I can eat – not what I can't." It is for this reason that IDDT introduced its most popular booklet, 'Diabetes – Everyday Eating' and 2 years later we have supplied

over 150,000 copies to people with diabetes and to healthcare professionals.

## March 2013, Issue 76, IDDT called on members to write to their MPs!

The National Audit showed that in 2012 there were no improvements in the standard of care received by people with diabetes on the previous year. In the restructured NHS, NHS Diabetes closed and diabetes was categorised just as a long-term condition rather than being treated as a separate condition.

IDDT called on its members to write to their MPs to ensure that people with diabetes are not sidelined and that the new NHS structure ensures that they are given priority to provide the much needed improvement in their treatment and care. Our members certainly raised awareness amongst politicians and Ministers of the needs of people with Type 1 and Type 2 diabetes.

## June 2013, Issue 77, IDDT launches the 'Passport for Diabetes in Care Settings'

With the numbers of people with diabetes in residential care being around 27%, IDDT recognised the particular set of difficulties faced by this group of people and those caring from them. Working closely with the Institute of Diabetes for Older People [IDOP], IDDT produced this new Passport. It draws together the essential elements of a person's care needs in relation to their diabetes into one simple, user-friendly document. This enables care staff to familiarise themselves with those needs quickly, easily and provides them with instruction on what to do if problems should arise. It aims to improve care and reduce preventable hospital admissions.

## September 2013, Issue 78, the launch of 'Type 1 diabetes – Know the Facts'

Following the success of our booklet 'Type 2 Diabetes – Management and Medication', IDDT launched this new booklet for people with Type 1 diabetes.

IDDT also advertised its first Diabetes Study Day for Healthcare Professionals with the aim of informing, inspiring and educating the healthcare community. It was rated a success by those who attended and a further study day is planned for 2014.

# Celebrate our anniversary by taking on a £20 challenge



We've launched the £20-year challenge to mark our 20th anniversary – and we're inviting you to take part.

IDDT has come along way in the last two decades. In the beginning it was a day-to-day battle. At one stage we couldn't even afford stamps, but as the word spread and our passion emerged, we became 'the' independent voice for people with diabetes.

Now in 2014, while our commitment and resolve is still absolute, in this present economic climate, we need your support to guarantee the continuation of our work.

Martin Hirst, acting IDDT Chief Executive, said: "We don't normally ask members to get involved in fundraising, and there is no obligation.

"However, if you want to get involved, any help, big or small, spectacular or modest, whatever you may choose, your efforts would be appreciated. Whether it's a marathon, readathon or coffee morning, we would be grateful for any effort made."

We were formed in 1994 to fight for the continued availability of animal insulin. Against the \$300-billion-a-year global pharmaceutical industry and UK government, we won an historic, 11-year, David versus Goliath campaign to secure choice of insulin for all.

In the early days it was all about our fight for animal insulin, but then we quickly started to realise there was a huge demand for across-the-board support for people with diabetes – independent support. The remit of IDDT began to grow.

Twenty years on and we have a free, confidential helpline, providing support to anyone affected by diabetes. We've published dozens of helpful and service-influencing publications. We stage events and lobby government on behalf of our members.

We've emerged as a fully-fledged charity, solely dedicated to the interests of our members and everyone living with diabetes. However, as with many charities we rely solely on donations and we need your support to secure our future.

**To get involved or to obtain one of our fundraising packs, visit our website [www.iddtinternational.org](http://www.iddtinternational.org) or call us on 01604 622837**

## You don't have to be energetic!

In addition to sporty challenges, here are a few fundraising ideas

Individual Challenges	Family Challenges	Friends' Challenges	Work-based challenges
Give something up. Slimming diet. Plant sale. Readathon. Jigsaw marathon. Coffee morning. Car washing. Jewellery making/selling.	Tombola. Treasure Hunt. Sponsored silence. Face painting competition Just put an IDDT collection box in your local shop or pub -we supply them.	Knitting competition. Flower show. Film night. Football competition. Cricket match.	Cake sale. Swear box. Walk or cycle to work. Fancy dress. Sponsored silence. Raffle. Quiz. Loud tie of the day. Dress down day. Football tournament. Cricket match.

### General Introduction

**T**HE INSULIN DEPENDENT DIABETES TRUST is a newly-formed registered charity concerned with listening to the needs of those living with diabetes, understanding those needs and doing its utmost to offer help and support.

We not only want to help those who actually have diabetes but also their carers – husbands, wives, partners and parents – all of us who 'live with diabetes'. We recognise that when one person in a family has diabetes, all the other family members are affected to a greater or lesser extent and they have views and needs too – perhaps different views and needs from the person with diabetes but just as important. We feel a collective database is needed to collect all information about the experiences of the good and bad aspects of treatment of those with diabetes and their carers. This database will then be used to inform drug companies, diabetes health care workers and politicians of the day-to-day needs of those with diabetes.

The Trust has been set up to look at some of the day-to-day difficulties of living with diabetes – the ones that many of us experience and understand because we actually live with diabetes – the worries, fears and concerns that perhaps we don't talk about at the clinic visit. Like any other charity, IDDT has to have trustees and with the exception of our Medical Adviser, Dr Laurence Gerlis, our trustees all live with diabetes – 3 have diabetes and 3 are carers. So we know at first hand that whilst diabetes doesn't rule our lives, it is an important part of them, it needs care and attention, it can be a nuisance and it's not without its problems!

We came together because we all have one thing in common – we all experienced problems with human insulin and when changed to animal insulin many of those problems disappeared. The problems were not only the well-talked-about loss of 'hypo' warnings but varied from increase in weight, extreme tiredness, aches and pains, loss of feeling, loss of memory, 'change in personality', less stable diabetic control (more 'hypos', some severe) – all of which made life difficult and sometimes depressing.

These experiences made us wonder how many more people are experiencing some of these problems and have not thought about changing their insulin to see if that helps remove the problems as it did for us. It also made us

very concerned that we should try to ensure that animal insulins continue to be produced not only for those of us who have changed to them because of problems but also for those who may need to change in the future and for all those who have always, and still are, using animal insulins.

We are also very aware that the lack of availability of the pen-injection system and animal insulin cartridges influences people to remain on human insulin when they would prefer to change. In the short time that IDDT has existed, we have made good progress on this matter – so read on!

You will see from the news items in this *Introductory Newsletter* that we need to be active now on these issues. At this stage we have no paid secretary and so we have to use an answerphone and fax. We know nobody likes them but please contact us with your experiences, concerns or even your offers of help! Letter, telephone or fax – we will be back to you as soon as possible.

We hope that this *Introductory Newsletter* will give you information, support and encouragement and that whether or not you are happy with your chosen insulins, you will support us in our efforts to ensure that all those who are dependent on insulin have an informed choice, the right to change insulins without fuss and an equal choice of injection devices.

**PLEASE SUPPORT US TO SUPPORT YOU**

## THE STORY SO FAR . . .

**HUMAN INSULIN FIRST BECAME AVAILABLE** in the early 1980s and over a relatively short period of time the majority of people were changed from animal insulin to human insulin; since then most newly-diagnosed people have been almost always automatically treated with human insulin.

Within a year or so of the changeover some people were reporting less warning signs of hypoglycaemia, more frequent 'hypos' and generally more problems in controlling their diabetes safely. As time progressed, other symptoms were being reported such as tiredness, feeling unwell and increase in weight. There are now people who appeared to be very well on human insulin for some years but who have since displayed these symptoms which disappeared when changed back to animal insulin.

As there appeared to be no scientific evidence to demonstrate a difference in the two types of insulins, the only evidence that existed has been classed as anecdotal - in other words the views of patients and their carers. To date the evidence is inconclusive and yet there are some people who experience problems with human insulin, although there is no scientific evidence to support them - there is equally no scientific evidence to dispute their experiences. The British National Formulary states that no real advantage has been shown by using human insulin. It is also important to note that most of the scientific research done puts diabetic patients under conditions never experienced in normal life, so the relevance of the research to living with diabetes in the 'real' world is very questionable.

### So What Are Our Problems And Concerns?

- ◆ Those who were on animal insulins and were changed can compare their diabetic control and their general well-being. What about those who have only used human insulin? They have no comparison to make and may accept erratic diabetic control as the best they can achieve and may also put how they feel down to just 'being diabetic'.
- ◆ Those for whom the symptoms come on gradually may well not associate these with human insulin and may well not consider changing to animal insulin to see if there is any improvement.
- ◆ That whilst there is no scientific evidence that shows a difference in the two types of insulins, anecdotal evidence is valuable and people with diabetes do know how they feel and their carers are valuable observers in any changes. Those of us who live with diabetes, need to be assured that the professionals looking after us are fully aware of this.
- ◆ Those who want to change to animal insulin should feel able to do so by discussion with their doctor and all those with diabetes should have an informed choice of which type of insulin to take.
- ◆ That those living with diabetes should feel secure that their chosen insulin will continue to be produced and that animal insulins will NOT be withdrawn from the UK.
- ◆ That people are not dissuaded from using animal insulins because they are not available in cartridges for pen-injection devices.

### INFORMATION ABOUT HUMAN AND ANIMAL INSULINS

**THROUGH OUR CONTACTS IN EUROPE** and letters from our MPs, we know that pork insulins have been withdrawn from some European countries, supplies to Holland have been restricted and the price of animal insulins in Germany has been significantly increased to equate to the price of human insulins. In Germany there is no NHS, so patients have to purchase their insulins and our feelings are that the increase in price is a way of artificially reducing demand.

#### What You Can Do

**IF YOU HAVE CHANGED YOUR INSULIN AND THE PROBLEMS YOU HAD WITH YOUR LAST INSULIN HAVE REDUCED OR DISAPPEARED, ASK YOUR GP TO REPORT THIS TO THE COMMITTEE ON SAFETY OF MEDICINES (CSM).**

Unfortunately, very few cases where those with diabetes have had severe problems with human insulin have ever been reported to the CSM. This is because doctors are very busy and may think your case has already been reported or are not sure whether the problem is related to human insulin. It is because of this gross under-reporting that the CSM has not been alerted to the frequency of the adverse effects experienced with human insulin.

**TO DO THIS:** Simply book a long appointment with your GP and ask him or her kindly to report your case. Say that you know he or she is very busy but please could they do it *especially* if you have changed to animal insulin and things have improved.

**WHEN YOU BECOME A MEMBER** of the Insulin Dependent Diabetes Trust we need you to fill in a short questionnaire and we also invite you to write us a letter with fuller information. This information is *vital* for us to build up a database of users' experiences with human and animal insulins. When we have adequate information, we hope to make a strong case to represent your views and feelings. The data should also give the most reliable information about insulin use because the experiences of patients and carers are those that count and have greater importance than any scientific research. We need large numbers, so please fill in and return the questionnaire when you receive it and encourage anyone else living with diabetes to join us and complete a questionnaire.

## GOOD NEWS!

The lack of a pen and animal insulin cartridges has concerned many of the people taking animal insulin and has even influenced people to stay on human insulin when they would have preferred to change. Lobbying has been unsuccessful and many different reasons have been given as to why cartridges are not being produced - cost and lack of demand being the main ones. However, in the short time that the Trust was formed, we have discovered that:

- There is a pen and there are cartridges of porcine velosulin available in some European countries and these have been available for several years. We do not know why they have not been available to the diabetic community in the UK.
- The pen can be purchased in the UK and the cartridges of porcine velosulin are prescribable on the NHS. Several of us are using them already.
- In correspondence with the producers, it is their intention to withdraw this pen by the end of 1994. But if enough of us in the UK use it, maybe the demand will be sufficient for them to think again!

#### So Here's How To Obtain Your Pen, Needles And Cartridges

For each purchase, please ensure that you provide us with your full name and address in **BLOCK CAPITALS**

**To purchase the 'Insuject' Pen:**

Send to us at IDDT, PO Box 294, NORTHAMPTON, NN3 2BN, a cheque or postal order for £40.80p, made payable to John Bell

and Croyden. We will then arrange for a pen to be obtained and sent to you within 2/3 weeks.

#### Needles For The 'Insuject' Pen

Needles are normally supplied in boxes of 100 but if necessary we can make special arrangements to supply smaller quantities.

**If you wish to purchase a box of 100 needles:**

Send to us at IDDT, PO Box 294, Northampton, NN3 2BN, a cheque or postal order for £20.66p, made payable to John Bell and Croyden. The needles will then be sent to you within 2/3 weeks.

**If you wish to purchase less than 100 needles:**

Send to us at IDDT, PO Box 294, NORTHAMPTON, NN3 2BN, a cheque or postal order made payable to the Insulin Dependent Diabetes Trust for the number of needles you require which can be supplied in multiples of 10 at £2.30p per 10. The needles will be sent to you within 2/3 weeks.

**NOTE:**

We realise that the 'Insuject' pens and needles are costly, so we are urgently seeking alternative and cheaper sources of supply.

#### To Obtain Cartridges On NHS Prescription

Book an appointment with your GP and ask him or her if they will prescribe the cartridges on a 'NAMED PATIENT' basis. You can tell them that some patients are already using this method. Your GP will have to write a letter which you take with your prescription to your pharmacist. Your pharmacist can then order the insulin from I.D.I.S., telephone 081 549 1355. The prescription should be written as **VELOSULIN PORCINE VIALS/CARTRIDGES 2.5ml, 5 in a box, for use with INSUJECT pens.**

## Beverley Hirst Interview

We recently talked to Beverley Hirst, aged 23, about her diabetes which she has had since she was 5 years old. When diagnosed, Bev used animal insulin and after about 8 years was changed to human insulin. Since then she has changed back to animal insulin.

**Q: Although you were quite young when you first changed to human insulin from animal insulin, were you aware of any changes in your diabetes?**

**Bev:** No.

**Q: So what made you change back to animal insulin 8 months ago?**

**Bev:** I didn't feel at all well and it was really as a last resort. I seemed to be always visiting my GP and had lots of tests but he couldn't find anything wrong and didn't give me any medication.

**Q: What do you mean when you say 'you weren't very well'?**

**Bev:** I felt constantly tired and depressed. I felt as though I had high blood sugars but they weren't. I had problems remembering things from one minute to the next and felt unable to hold a conversation. I felt inadequate and a sort

of numbness and separate from what was going on around me. On top of this I put on a lot of weight quite quickly.

**Q: So what happened then?**

**Bev:** Because I'd heard rumours about human insulin affecting people differently, as a last resort I changed to animal insulin and at this point if this hadn't worked, I don't know what I would have done. My GP was happy to change me back to Velosulin and Insulatard - pork insulins.

**Q: How did things change then?**

**Bev:** I did roughly the same doses of animal insulins and within 3 days felt a completely different person. I was able to get up in the mornings and felt awake - for the first time in about 4 years. My depression went away, there was pinkness in my cheeks and I generally felt a lot fitter and healthier.

**Q: What happened over a longer period?**

**Bev:** I lost weight almost straight away and over 6 months have lost nearly 3 stones - without dieting. My memory went back to normal or as it should be. I became more aware of what was going

on around me and I felt able to include myself in this and could hold conversations again with confidence.

**Q: What about 'hypos'?**

**Bev:** All my old warnings came back - dizziness, cold sweats, irritability. I hadn't quite realised I'd lost them until they came back, because they had disappeared gradually.

**Q: So were there any other changes that happened that you wouldn't have put down to altering your insulin?**

**Bev:** Yes. I easily got infections, frequent tonsillitis, cuts always went badly septic. I had regular stomach upsets which have stopped since I changed. I suffered badly with constipation for 4 years and never had regular periods all this has changed dramatically.

**Q: Finally, have you any comments you'd like to make?**

**Bev:** Yes. I'm fully aware that human insulin agrees with some people but for me human insulin was crippling and therefore people should have the choice of insulins and be given the knowledge of people who have suffered.

## Starting Out

**T**HERE ARE MANY WAYS in which you can help and support us. The first and most important is by becoming a member and filling in our questionnaire, whether you have diabetes or whether you are a relative or friend of someone who has. So often, helping a charity means merely giving or raising money and whilst that is important for us as a new charity, there are many other ways in which you can help which are equally valuable. You may have knowledge, skills or facilities in your job which would be useful to us - for instance, one of our members has a means of buying envelopes very cheaply and another who has previously worked for a charity has saved us a great deal of effort and money by using his knowledge of the legal aspects of running a charity. We all have many ways of helping - perhaps there are ones you didn't think you had!

### PUBLIC RELATIONS

- ★ Could you help in dealing with the press, radio or TV, either nationally or locally?
- ★ Could you help with our Newsletters and publicity material?
- ★ Do you have graphic design skills?



### LOCAL CONTACT FOR IDDT

- ★ Are you someone that people in your area could talk to?
- ★ Someone who could help circulate information about IDDT and its aims?
- ★ Someone who could distribute information to GP's surgeries?

### BORING JOBS!

These jobs may be ordinary but they are still very important - 'Stuffing' envelopes, photocopying, etc., etc. - can you help?



### FUNDRAISING AND SPONSORSHIP

Can you:

- ★ Hold a coffee morning?
- ★ Organise a jumble sale?
- ★ Run a marathon?

Any event, however large or small, will provide funds to assist the charity to carry on its work.



The Trust is a 'patient-centred' organisation based on true self-help. If we all help just a bit, in whatever ways we can, we will achieve our aims.

If you can help in any way at all, please contact:

Sue Wren (if you live in the North) or Sue Morris (if you live in the South) at IDDT, PO Box 294, Northampton NN3 2BN. Telephone and Fax 0604 721325.

## POSTSCRIPT

We hope you have found this Introductory Newsletter helpful and we look forward to producing further newsletters at regular quarterly intervals. We'd love to hear your news and views so that we can develop a regular 'letters' column. Contact: Jenny Hirst at IDDT, PO Box 294, Northampton, NN3 2BN. Telephone and Fax 0604 721325.

# Taking on the £20 Challenge



Oliver Jelley is running from Market Harborough to Northampton

Oliver Jelley, better known as 'Olly', has taken on a £20-fundraising challenge to celebrate IDDT's 20-year anniversary. On Saturday, June 7th, 32-year-old Olly is going to run the 14-mile journey from Market Harborough to Northampton along the disused railway line between the towns, now known as the Brampton Valley Way.

Olly told IDDT: "Although I play a lot of sport, the most I have ever run is five kilometres, so I've let myself in for a quite a challenge. IDDT works tirelessly in the name of people with diabetes, helping to make their lives easier. I am a dedicated supporter and am proud to be taking in this challenge to help to guarantee the continuation of IDDT's work providing vital independent support for people with diabetes, their parents and carers."

To sponsor Olly visit: <http://www.justgiving.com/oliverjelley> or contact IDDT on **01604 622837**

## Insulin for Life and Dream Trust

Last year IDDT continued to work with an international organisation called 'Insulin for Life' to collect unwanted, unopened and in-date insulin and diabetes supplies.

These are distributed to clinics in developing countries where adults and children cannot afford the lifesaving insulin they need. In 2013 we managed to collect and distribute over 4600 pen cartridges and vials of insulin and nearly 10,000 blood glucose test strips, all of which would simply have gone to waste without organisations like Insulin for Life.



We also continued to co-ordinate our Sponsor a Child Scheme which encourages people to sponsor a child that is cared for by the Dream Trust Hospital in India. The support for the Dream Trust has gone from strength to strength with over 75 sponsors supporting 28 children and young people to provide the £17 a month needed by each child to buy life-saving insulin, their medical care and help towards their educational needs.

If you would like to help by sponsoring a child or if you have unwanted insulin and other diabetes supplies, contact IDDT on **01604 622837**, write to IDDT, PO Box 294, Northampton NN1 4XS or email [enquiries@iddtinternational.org](mailto:enquiries@iddtinternational.org)

# And from the past...

A true story but still brings a smile – but maybe you have to be a parent.

Two little brothers, both with Type 1 diabetes, were asked by their nice young doctor: *“So what’s new since your last visit?”*

Answer: *“We’ve figured out how to eat a chocolate bar and not have high blood glucose before supper.”*

*“How do you do that?”*

Answer: *“We save it and eat it before going to bed.”*

**From October 1998 but still useful today .  
Home blood glucose measurements can be affected by:**

- Anaemia [low level of red blood cells]
- Polycythaemia [high level of red blood cells]

**Blood test results can also be affected by:**

- Dehydration, especially important during illness
- High levels of fatty acids
- Oxygen saturation of the blood.

Most of the non-medical causes of false readings we cited in 1998 have been eliminated by improvements in meters, nevertheless if your HbA1c results don't seem to match your home blood glucose results, then it is worth looking at your testing technique or other factors.

# Topics we have debated over the years

There are topics that have been regularly discussed in our Newsletters because they have been raised by you, our readers and the people who call IDDT. These are the use of aspartame, statins and aspirin, so here is the latest news we could find.

## Aspartame considered safe

Over the years there has been much controversy over the sweetener, aspartame which is used in fizzy drinks in particular. However, the European Food Safety Authority [EFSA] has published an opinion stating that aspartame and its breakdown products are safe for human consumption at current levels of exposure. Their experts have carried out a detailed analysis of all available information and have concluded that the current Acceptable Daily Allowance of 40mg/kg bw/day is protective for the general population. The exception is people with a condition, phenylketonuria [PKU] who should adhere to a diet low in phenylalanine, an amino acid found in proteins.

Experts have ruled out a potential risk of aspartame causing damage to genes and inducing cancer and also concluded that aspartame does not harm the brain, the nervous system or affect behaviour or cognitive function in children or adults. For women who are pregnant, there is deemed to be no risk to the developing foetus from exposure to phenylalanine derived from aspartame at the current Acceptable Daily Allowance. [EFSA press release]

IDDT's only comment would be that this does not recognise the people who know they have adverse effects when consuming aspartame and nor do most of us know how much we are consuming in a day as 40mg/kg bw/day is meaningless to us ordinary mortals!

## Statins again – time to bust the myth about saturated fat

Over the years, IDDT has received numerous queries about statins not least because of the adverse effects they cause some people. Regular readers will also remember the Newsletter reported the government recommendations that everyone over 45 should take statins for prevention of heart disease was described by some as the largest clinical study ever. They were also introduced without evidence to back them up.

Dr. Aseem Malhotra, intervention cardiology specialist registrar at Croydon University Hospital, has reported that scientific evidence shows that advice to reduce saturated fat intake has surprisingly increased our cardiovascular risks. He says the UK government's obsession with levels of total cholesterol *“has led to the over-medication of millions of people with statins and has diverted our attention from other risk factors.”*

Dr Malhotra states that recent studies have not supported any significant association between saturated fat intake and the risk of cardiovascular disease. Instead, saturated fat has been found to be protective. He also asks the question that perhaps many of us have been asking, 8 million people in the UK take statins regularly, so why have there been no reductions in heart disease during this period?

Cholesterol has been classed as 'bad' since the 1970s when a landmark study concluded that there was a correlation between incidence of coronary heart disease and total cholesterol. However, Dr Malhotra points out that a correlation is not the same as cause. Despite this we were advised to reduce fat intake by 30% of total energy and a reduction in saturated fat of 10%. The food industry compensated by replacing saturated fat with added sugar and it is this that is partly responsible of the obesity epidemic.

A recent *JAMA* study revealed that a “low fat” diet showed the greatest decrease in energy expenditure, an unhealthy lipid pattern, and increased insulin resistance compared with a low carbohydrate and low glycemic index diet.

It is important to recognise that adopting a Mediterranean diet after a heart attack is almost three times as powerful in reducing mortality as taking a statin and according to Dr Malhotra, “Doctors need to embrace prevention as well as treatment. It is time to bust the myth of the role of saturated in heart disease and wind back the harms of dietary advice that has contributed to obesity.” [BMJ Oct, 2013]

**Where does this leave patients?** This is a question we frequently raise but perhaps the answer is becoming more obvious – the Mediterranean diet and plenty of exercise as this raises levels of 'good' cholesterol.

## Aspirin – the US makes its mind up

For several years, there has been debate about whether people with diabetes should take daily aspirin to reduce the risk of cardiovascular disease. People with Type 1 and Type 2 diabetes are at 2 to 4 times greater risk of cardiovascular disease than people without diabetes.

Aspirin is an anti-clotting agent so can prevent blockages in blood vessels which can lead to heart attack or stroke. However, it does have adverse effects in some people, the most common being intestinal bleeding because it irritates the lining of the stomach, therefore the debate is whether the risk of bleeding outweighs the benefits.

Published research [BMJ Open, April 2013] adds more to the debate. The researchers observed that people with diabetes without cardiovascular disease may not get any benefit from daily aspirin and it may do more harm than good.

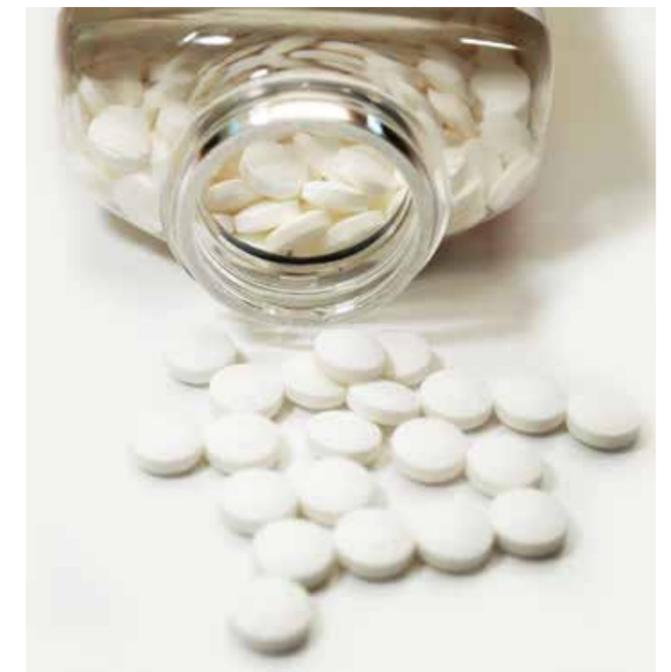
- There was no link between aspirin use and beneficial effects on risks of cardiovascular disease or death.

- When looking at the information for women only, the women who took aspirin regularly had a slightly greater risk of cardiovascular disease or death than women who did not take aspirin. This increased risk did not occur in men.
- Aspirin was associated with a significant increased risk of gastric ulcer in the whole group and in women.

The Americans have made up their minds about aspirin use and the American Diabetes Association and the American College of Cardiology have issued a joint statement of recommendations.

- Low dose aspirin is reasonable for adults with diabetes who are at increased risk of cardiovascular disease and not at an increased risk of bleeding. This includes men over 50 and most women over 60 years old.
- Aspirin is not recommended for adults with diabetes who have a low risk of cardiovascular disease, such as men under 50 and women under 60 years old with no major risk factors.
- Aspirin might be recommended in people at an immediate risk of cardiovascular disease.
- The recommended aspirin dose is 75 -162mg daily.

However, the important recommendation is that treatment with aspirin should be based on a patient's individual health, their family history, cardiovascular risk factors as well as their medication history. Therefore it seems the blanket recommendations that adults with diabetes should take aspirin are no longer appropriate.



# Treating people as individuals

Recent research has shown that improving communication and education in the clinic of people with Type 2 diabetes over the age of 70 improves diabetes control.

The research at the University of Exeter and published in The Lancet showed that 27% of people achieved better diabetes control through what is described as 'individualised care' compared to standardised treatment which does little to take into account their complex health needs. So by simply improving communication and education in the clinic, people benefitted.

The head of the research said, "People over the age of 70 are more likely to have multiple complications, such as heart disease, as well as Type 2 diabetes. Yet pervasively, these patients have so far been excluded from clinical trials, precisely because of these complications."

*It means they are generally treated with a 'one-size-fits-all' approach. We found that simply by individualising goals and setting realistic targets, then spending time talking to patients rather than aggressively chasing targets resulted in nearly a quarter of patients achieving better glycaemic control, without the need for medication."*

The advantage of this study is that it provides evidence to support the case for treatment to be individualised, which has so far been lacking.

## However, IDDT comments...

IDDT is well aware that older people with Type 2 diabetes are all too often excluded from research and therefore the evidence for the best treatment is lacking. However, it is not rocket science to know that people are individuals and are different, so why is it assumed that people with diabetes should be treated any other way than as individuals? Whether old or young, whether they have Type 1 or Type 2 diabetes, each person is an individual and will deal with the fact that they have diabetes differently, their lifestyle will be individual to them and of course, how they manage their diabetes will be individual to them.

So the question has to be asked; is it ever right to treat people with Type 1 or Type 2 diabetes with a 'one-size-fits-all' approach? Would we not all benefit from being treated as individuals? This in turn, would automatically improve communication between the health professionals and patients, which surely is better for everyone.

Is the reason this doesn't happen because the NHS could not cope or is it a real belief that people with diabetes of any age are all alike?

## Note: while we are talking about age – disability badges for your car

For people who have disability badges for their cars, this is just to make you aware that you will no longer be sent a reminder to renew your badge. It has become your responsibility to remember to renew at the appropriate time.

# Pharmaceutical News

## New long-acting insulin from Sanofi

Sanofi Aventis, the manufacturers of Lantus [glargine], has developed a new long-acting insulin called U300. It is claimed to be better than Lantus, which loses its patent in 2015. Sanofi is expected to seek regulatory approval for U300 in the US and Europe in 2014.

The Phase III 6 month trial results, presented at the World Diabetes Congress 2013, showed that U300 requires less frequent or lower dosing than Lantus, has a more consistent insulin release, controlled low blood sugars better at night and lowered the incidence of hypoglycaemia at any time of day. It is similar to Novo Nordisk's new insulin Tresiba [degludec].

## The US reverses the decision on Avandia

Readers may remember that Europe and the US put restrictions on the use of the Type 2 drug, Avandia, after evidence suggested that it increased the risk of heart attack. However, in November 2013 the Food and Drug Administration [FDA] in the US lifted these restrictions after receiving new evidence that Avandia does not increase the risk of heart attack.

This decision is not without controversy as Dr Steven Nissen who first raised the concerns about Avandia, says the decision is more about the FDA saving face and a single reanalysis of a trial does not exonerate a drug where all the other data point to increased cardiovascular risks. In 2007 Nissen carried out a study that pooled the results of 42 studies and this showed a higher risk of heart attack among patients taking Avandia compare to other diabetes drugs.

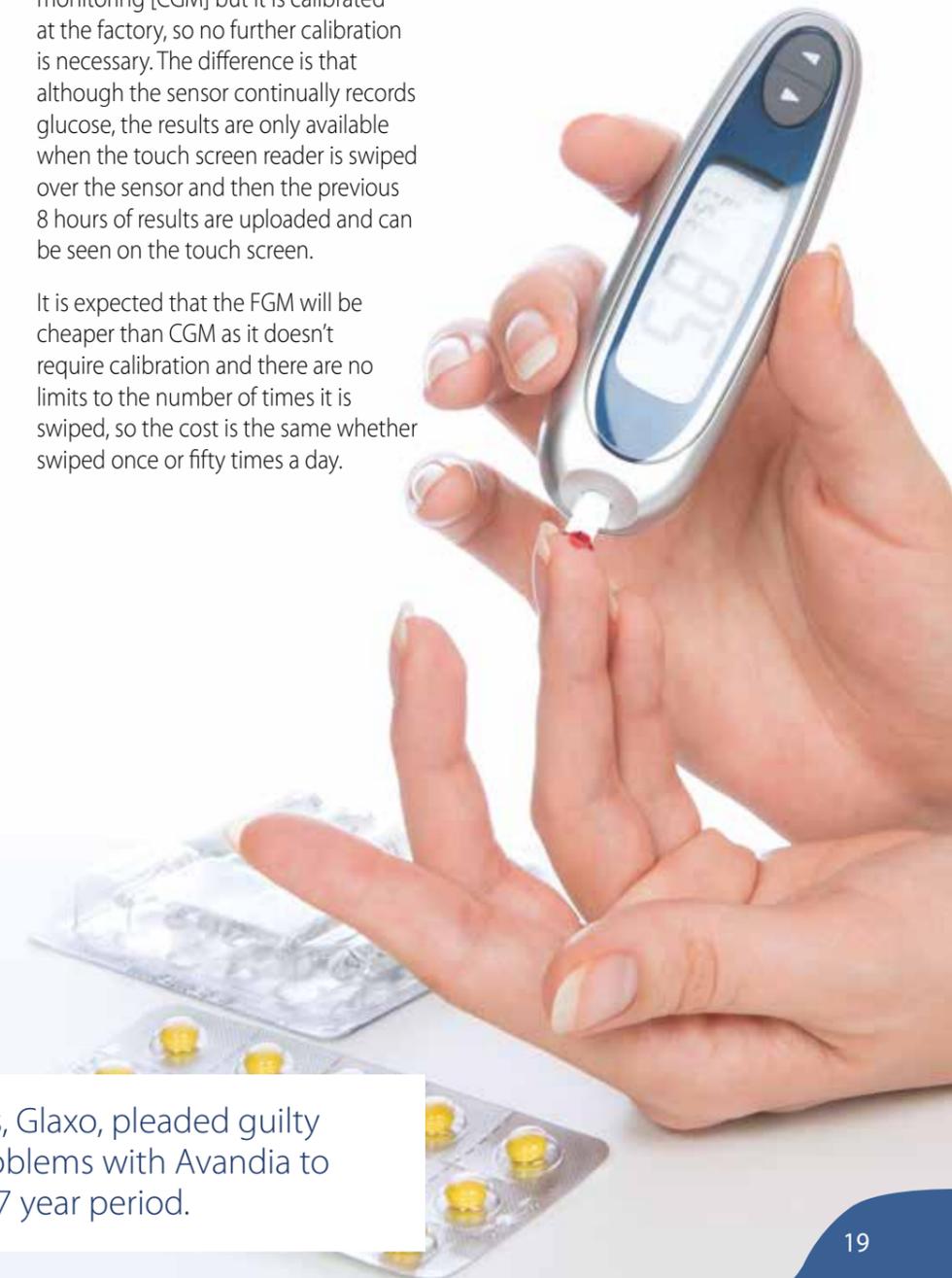
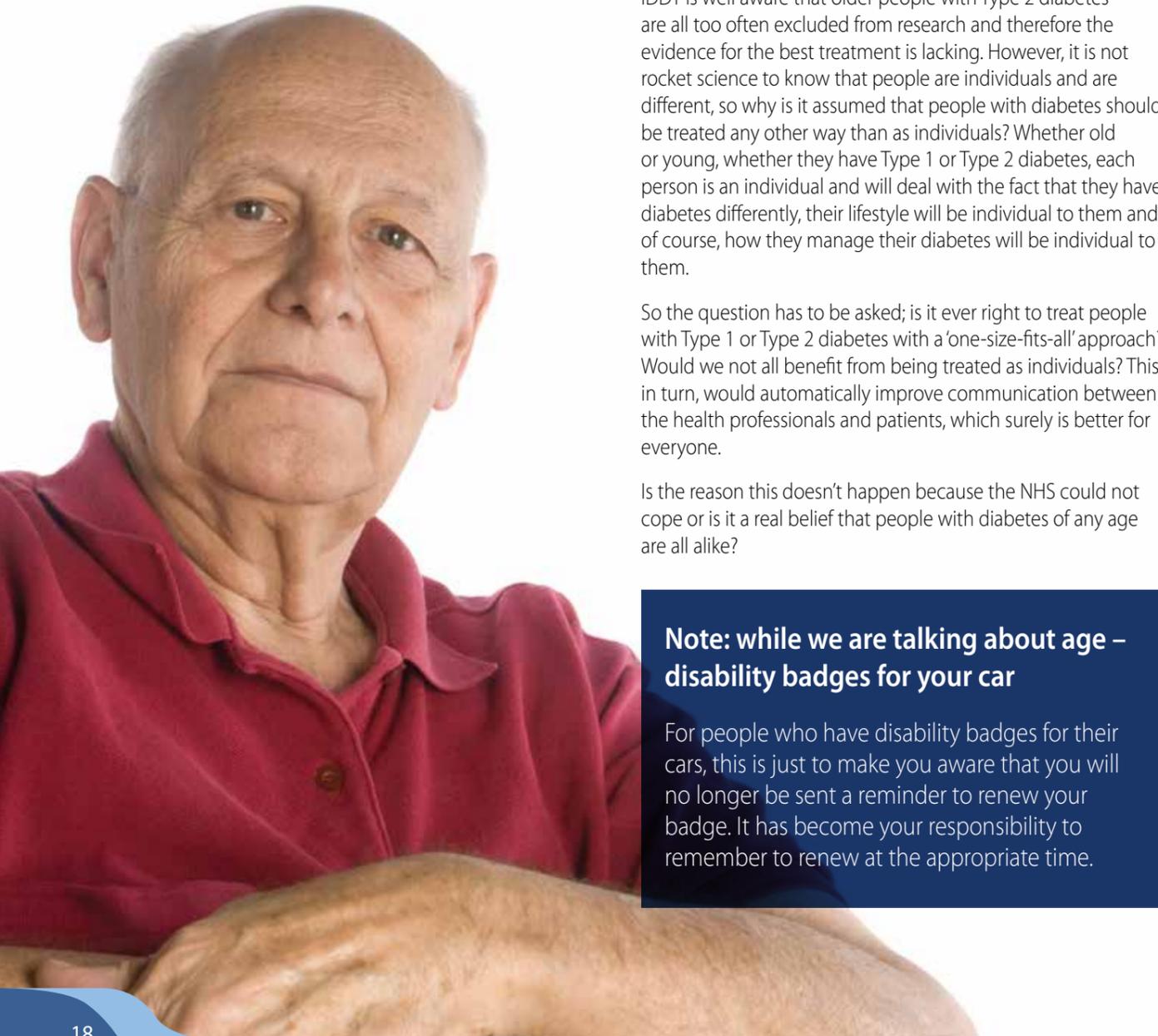
Note: in 2012 manufacturers, Glaxo, pleaded guilty to failing to report safety problems with Avandia to government officials over a 7 year period.

## Abbott develops new flash glucose monitoring

Abbott is developing a new type of glucose monitoring called the flash glucose monitor [FGM]. It consists of a sensor worn anywhere on the skin for a 2 week period. The sensor is similar to the one used with continuous glucose monitoring [CGM] but it is calibrated at the factory, so no further calibration is necessary. The difference is that although the sensor continually records glucose, the results are only available when the touch screen reader is swiped over the sensor and then the previous 8 hours of results are uploaded and can be seen on the touch screen.

It is expected that the FGM will be cheaper than CGM as it doesn't require calibration and there are no limits to the number of times it is swiped, so the cost is the same whether swiped once or fifty times a day.

The disadvantages are that it has no alarms, such as an alert for hypoglycaemia but parents could swipe their children while they are asleep or teachers could do it in class. It would also be useful for residents in care homes if it is hard get a standard blood test. It is hoped that it could be available by the end of 2014.



# More about food

## Counting fat and protein as well as carbs for Type 1 diabetes

A small Australian study has shown that meals high in fat or protein cause hyperglycaemia [high sugars] in children on intensive insulin treatment and they add to the post-meal rise in blood glucose levels.

The researchers found that the mealtime insulin dose is calculated exclusively on carbohydrates. However, there is growing evidence that nutrients other than carbohydrates influence post-meal glucose levels and insulin requirements. They concluded that proteins and fat should be considered in the meal time insulin doses.

The study showed:

- There was a significant reduction in hypoglycaemia after high-protein meals but no reduction after high-fat meals.
- Meals high in both protein and fat cause hyperglycaemia.

Earlier research has shown that high fat meals with identical amounts of carbohydrate and protein required more insulin than low fat meals and despite additional insulin, they caused more hyperglycaemia in people with Type 1 diabetes. [Diabetes Care 2013;36:810-6].

Another small study of only 7 people with Type 1 diabetes with an average age of 55 years showed that high fat dinners required more insulin than low fat dinners. Those who ate high-fat dinners had higher glucose levels even 5 to 10 hours after dinner and the insulin requirements increased on average by 42%.

The researchers point out that in Type 1 diabetes, these studies highlight the limitations of mealtime insulin doses that are solely based on carbohydrate intake. Fats as well as carbohydrates need to be included to obtain the best glucose control. [Diabetes Care, 2012; 36 (4): 810]

## Combination of low carb and the Mediterranean diet can slash the risk of Type 2 diabetes

New research involving over 22,000 people over 11 years has shown that combining a low-carbohydrate diet and Mediterranean-style eating habits can cut the chances of developing Type 2 diabetes by 20%. The Mediterranean diet is high in fruit, vegetables, fish, nuts, whole grains and virgin olive oil while cutting back on meat and dairy products. The low carbohydrate diet involves cutting back on foods such as bread, potatoes and pasta.

Both diets have been shown to be beneficial:

- The low carb diet has a marked effect on weight loss and helps to improve cholesterol levels and blood pressure.
- Several studies have shown that the Mediterranean diet improves heart health, lowers the risk of stroke and can stave off cancer. [Diabetologia, August 2013]

IDDT has always questioned the thinking behind the recommended high carb diet, especially for people with diabetes. There is now sufficient evidence to show the

benefits of the Mediterranean diet, it is surprising that the dietary recommendations for the UK never seem to change.

## Caution about red wine and dark chocolate being 'healthy'

Widespread press reporting that consuming red wine and dark chocolate lead to a reduced risk of developing Type 2 diabetes could be misleading. This came from a study looking into the actions of chemicals known as flavonoids found in foods such as berries, apples, pears, onions and in both red wine and dark chocolate. Although the study showed an association between a higher intake of flavonoids and the risk of Type 2 diabetes, this does not prove a definite link. There are also concerns that the calorie content of wine and chocolate would outweigh any possible benefits. So not time to start guzzling wine and chocolate! [Journal of Nutrition, January 2014]



## The drugs affected by grapefruit and grapefruit juice increases

It is well known that some people should avoid grapefruit and grapefruit juice because there is a harmful interaction with the drugs they are taking. The list of drugs with the potential to cause serious harm by interacting with grapefruit has risen sharply from 17 to 43 between 2008 and 2012. [Canadian Medical Association Journal]

More than 85 drugs can interact with grapefruit and of these 43 can have serious side effects. Chemicals in grapefruit [furanocoumarins] act on an enzyme in the gut which can increase the potency of some drugs so effectively boosting the dose many times over. For example, research showed that a combination of the cholesterol-lowering drug, simvastatin, and a 200 millilitre glass of grapefruit juice once a day for 3 days, more than tripled the concentration level of the drug.

One of the problems is that when prescribing drugs, doctors are often unaware if people consume grapefruit or grapefruit juice and patients don't tell them because they are unaware of the significance of grapefruit! The list of 'danger' medicines includes treatments for anxiety, depression, allergy, HIV infection, seizures, heart rhythm abnormalities and high cholesterol.

## The role of cinnamon

Research published in the Annals of Family Medicine showed that people with Type 2 diabetes who took cinnamon supplements had improvements in cholesterol levels and slightly lower blood glucose levels than those who took the Type 2 drug, sitagliptin. However, cinnamon extracts were not better than metformin in reducing glucose levels and did not show significant improvements in HbA1c levels. As the long-term effects of cinnamon are unknown, the researchers do not recommend replacing diabetes medications with cinnamon.

## Cider vinegar drink may have blood glucose benefits

A study investigated the effects of apple cider vinegar and found that participants who drank apple cider vinegar daily for 12 weeks achieved significant reductions in fasting blood glucose levels compared with those who did not drink it. The researchers suggest that including vinegar [acetic acid] into the food eaten, beyond the standard dressings and sauces, may reduce blood glucose concentrations in those diagnosed with Type 2 diabetes and those at risk of it. [Journal of Functional Foods, September 2013]

# Type 2 diabetes and the effects of tight control

Recent studies have raised questions about the benefits of tight control or aggressive treatment of Type 2 diabetes. These are almost the same thing, 'tight control' means aiming for near-normal blood glucose levels and 'aggressive treatment' means using several drugs and possibly insulin to bring blood glucose down to near-normal levels. Both can increase the risk of hypoglycaemia and in some cases, cause severe hypos. In addition, research raises other issues and below are three studies which warrant further examination.

## People with Type 2 diabetes with severe hypoglycaemia are at a higher risk of cardiovascular disease

A study published bmj.com [July 31st 2013], suggests that avoiding severe hypoglycaemia may be important to prevent cardiovascular disease [CVD] and that "less stringent glycaemic targets may be considered for people with Type 2 who are at high risk of hypoglycaemia." The results of 2 studies that were analysed, including 903,510 people with Type 2 diabetes, showed that between 0.6% and 5.8% experienced severe hypos during the one to five years that they were followed up.

The researchers concluded that severe hypoglycaemia in Type 2 diabetes is associated with a 2 fold increased risk of cardiovascular disease. They said that the choosing treatment with a low risk of causing hypoglycaemia, patient education and self-monitoring of blood glucose can be useful in preventing hypoglycaemia. This in turn may be important to prevent cardiovascular disease.

## Insulin and sulphonylurea drugs are the second most common cause for emergencies

A national study carried out in the US has found that overtreatment

of high-risk, older people with diabetes is very common. The "high-risk" diabetes patients were defined as those receiving insulin and/or sulphonylurea therapy who are at least 70 years of age, have renal impairment or have been diagnosed with cognitive impairment or dementia.

Dr. Pogach, national program director for endocrinology and diabetes at the Veterans Health Administration, cited a 2011 report that showed that insulin and sulphonylurea drugs combined is the second highest cause of emergency admissions to hospital and second only to warfarin. [N. Engl. J. Med. 2011;365:2002-12]

In the study overall, 48% of these high-risk diabetes patients were being over-treated, as the HbA1c was below 7.0%. Moreover, 25% of the high-risk group had an HbA1c below 6.5%, and 10% had an HbA1c of less than 6.0%

The American Geriatrics Society recommends that medications other than metformin are not routinely used to lower HbA1cs below 7.5% in patients older than 65 years and the HbA1c target of 8%-9% should be used for people with additional serious health conditions. The American Diabetes Association also now recommends an HbA1c target of 7.5%-8.0% or slightly more in people at increased risk for serious hypoglycaemia or with reduced life expectancy, rather than its former universal goal of less than 7.0%. [Presented at the annual scientific sessions of the American Diabetes Association 2013]

## Aggressive glucose control in Type 2 diabetes

A large study which followed 58,000 adults with Type 2 diabetes for 4 years has shown that more aggressive strategies for controlling blood glucose levels have variable short term effects but they do not reduce the rate of heart attacks or preservation of kidney function over 4 years.

The participants had HbA1cs of less than 7% by taking two or more oral drugs or long-acting insulin. Subsequent HbA1c levels increased from 7% to 8.5%, so treatment was intensified eg more drugs and/or insulin. The researchers found that initially this reduced the onset or worsening of albuminuria [protein in the urine] but over the 4 years this intensification of treatment did not result in reductions of major complications of diabetes, such as the occurrence of heart attacks or the preservation of kidney function. These findings are similar to other studies which question the benefits of tight blood glucose levels with several medications in Type 2 diabetes. [Diabetes Care, July 2013]

## Let's not forget insulin adverse events in the US

Another national analysis in the US has shown that older adults with diabetes are particularly vulnerable to insulin adverse events which lead to A&E visits. The adverse events were either hypoglycaemia or accidental dose errors.

Compared to people with diabetes aged 45 to 64, those over 80 years were 2.5 times more likely to visit A&E with an insulin adverse event and about 5 times more likely to be admitted.

- Patients aged 45-64 years had the highest number of A&E visits (35%), followed by those 65-79 years (25.3%), 18-44 years (21.7%), 80 years or older (15.8%), and younger than 18 years (2.1%).
- Still, patients 80 years or older had a rate of 34.9 A&E visits per 1,000 diabetic persons, far surpassing rates observed among those younger than 18 years (13.7), 18-44 years (24.3), 45-64 years (13.7), and 65-79 years (16.3).

# RESEARCH NEWS

## People with Type 1 diabetes may still produce insulin

Recent research has shown that about 75% of people with Type 1 diabetes have a small number of beta cells that still produce insulin in response to food. This suggests that not all the insulin-producing beta cells in the pancreas are killed by the immune system or that the beta cells are regenerating themselves. New technology has been able to measure very small concentrations of insulin in the blood by testing for C-peptides. [Diabetologia, October 2013].

## Google testing 'smart contact lens' to monitor blood glucose levels

This contact lens uses a combination of two electronic chips, a sensor and a tiny antenna embedded in flexible plastic and sandwiched between two layers of the material used in normal contact lenses.

There is a tiny pore in the inner layer of the lens and tears flow through this on to the glucose sensor. Glucose readings are then transmitted to the wearer's smart phone via the antenna. For those without a smartphone, it may be possible to include a small LED light which could signal colours only seen by the wearer.

This received a lot of press coverage, but Google who is funding the research, say that there is a lot more work to do to turn this technology into a system that people can use. So let's not get excited yet!

## Implant invention to prevent insulin injections

This British invention is a wristwatch-size device which is surgically implanted into the abdominal cavity and releases a precise amount of insulin into the bloodstream. Supplies are topped up via a short tube which passes through the skin.

According to Professor Joan Taylor of De Montfort University Leicester, the device works like a healthy pancreas should and regulates blood sugars by releasing just enough insulin into the bloodstream and it doesn't need filling up everyday. The implant contains a reservoir surrounded by a special gel which slowly releases insulin as blood sugar levels rise. As levels drop, the gel solidifies, ensuring the right amount of insulin is released. It is not powered by batteries or electronics and has no moving parts, so the risk of rejection is very low.

Human trials are set to start in 2016 and it is hoped that the first implants will take place on the NHS in about 10 years at a cost of £5,000 for the device and the surgery to fit it. It is an exciting project which not only removes injections but also some of the stress related to making decisions about insulin doses.

## Research supports the possibility that a vaccine may prevent the onset of Type 1 diabetes

Type 1 diabetes occurs when the body's immune system destroys the insulin-producing beta cells. The cause of this remains unclear but there is a belief that enteroviruses may play a part. Research shows the most likely is a group known as B coxsackieviruses. Two studies have shown an association between Type 1 diabetes and this specific virus group which is known to damage beta cells. The next step is to find out if children with Type 1 diabetes actually had these viruses. This would show a cause of Type 1 diabetes rather than just an association between the virus and Type 1 diabetes. [Diabetes, October 2013]

## Insulin pill a step closer

Israel's Oramed oral drug delivery specialist has announced that a small study into its insulin capsule produced successful results and a larger mid-stage study is now planned. The idea of an insulin pill has been around since the 1930s but it is difficult to achieve because the insulin is destroyed by the digestive system. Oramed believes it has found a solution to allow enough insulin to survive. Unlike injected insulin, the ingested form passes into the liver which then regulates the secretion of insulin into the bloodstream.

The new study will be in people with Type 2 diabetes and will mainly test for the drug's effectiveness. The company does not claim that the pill will totally remove the need for injections but it could make it easier for people to start early treatment, slow progression of the condition and delay the need for injections.

Oramed will also need to conduct a final large-scale Phase III trial before the drug is licensed for sale, so the capsule is still a long way off. There are also plans for early studies in people with Type 1 diabetes. The company is, however, ahead of Novo Nordisk who is also working on an insulin pill.

## Type 1 diabetes patients frequently have chronic fatigue

A study published in Diabetes Care [August 2013] suggests that people with Type 1 diabetes are more likely to experience chronic fatigue. In the study 428 people underwent a fatigue severity test and 40% of those with Type 1 diabetes reported chronic fatigue over the previous two weeks compared with only 7% of those in the control group without diabetes. The severity of fatigue was also significantly greater in the diabetes group.

## Type 1 diabetes drug effective in clinical trial

A new drug, teplizumab, designed to block the advance of Type 1 diabetes in its earliest stages is being said to be 'strikingly effective' after phase II clinical trials at the University of California. However, the people who benefited most were those who still had good control of their blood sugar levels and only a moderate need for insulin injections when the trial began.

The drug did not work for everyone - about half were able to maintain their level of insulin production for 2 years and the other half lost their ability to produce insulin in a similar way to the control group of participants who did not take the drug. The reasons for this are unknown but it could be the differences in the metabolic conditions of the study participants and in the severity of their condition at the start of the trial. [Diabetes, August 2013]

## Blood glucose control in women

A large international study presented at the European Association for the Study of Diabetes [Sept 2013] found that women with Type 1 diabetes are more likely to miss their blood glucose targets than men. The study looked at information from more than 140,000 people in 12 countries and found a greater proportion of adult women had poorly controlled HbA1c levels compared to men. Almost three quarters of women aged 15 to 29 years had HbA1c levels of 7.5% [58mmol/mol] or over. The UK researchers said the findings could be due to differences in haemoglobin levels between the sexes. [If this is the case, does this mean that HbA1c targets should be different for men and women??]

## Why metformin works in some people more than others

Metformin is the first line drug treatment for Type 2 diabetes [it is also sometimes prescribed in addition to insulin for people with Type 1 diabetes]. However, in Type 2 diabetes it works better at lowering blood glucose levels in some people than others. Researchers at Dundee University used information from 3736 people to look for gene variants linked to glycaemic response by measuring the reduction in HbA1cs within 18 months of starting metformin treatment.

The results showed that 36% of the difference in glycaemia response to metformin across the people could be explained by inherited genetic variation. This suggests that the response to metformin is more strongly linked to genetic factors than to the person's height or age of diagnosis. Much wider studies are needed to identify other genes responsible for the effectiveness of metformin. [European Association for the study of Diabetes, 2012].

## Investigating a new treatment for retinopathy

Moorfields Eye Hospital is one of 11 centres throughout Europe that is carrying out a trial of a new treatment for retinopathy. It uses a drug in the form of eye drops which is significantly less invasive than other treatments.

There is increasing evidence that degeneration of the nerves of the retina plays an important role in the onset of diabetic retinopathy, so the trial is looking into the safety and effectiveness of eye drops given at an early stage in the development. The research is due to be completed by February 2016.

## Statins linked to increased risk of cataract

A study reported in GP News [30.09.13] suggests that people taking statins face an increased risk of developing cataracts. This is because statins may interfere with cell development in the lens of the eye, a process which requires cholesterol for the lens to remain transparent.

In the study, 6,972 statin users were matched with an equal number of non-statin users and the analysis showed that the risk of cataract was 9% higher in people who had taken statins for at least 3 months, than in non-users. In healthy people with no other health conditions the risk was 27% higher in statin users. The researchers emphasised the importance of balancing the benefits and risks of statin use.

Note: At least 300,000 cataract operations are carried out each year in the NHS although a study by Imperial College London found that in 2012 almost half of all PCTs had unfairly restricted access to cataract surgery. [JAMA Ophthalmol Online 2013]

## Spouses of people with Type 2 diabetes more likely to develop the condition

Research carried out in Canada has shown that spouses of people with Type 2 diabetes have a 26% increased risk of developing the condition themselves. It also showed that men of spouses with diabetes are at greater risk of undetected Type 2 diabetes because they are less likely to have health checks than women.

The researchers suggest that many behaviours that lead to Type 2 diabetes, such as poor eating habits and lack of exercise, are shared within a household. They suggest that the diagnosis of one spouse may warrant increased surveillance in the other. In other words, when someone is diagnosed with Type 2 diabetes, it is a good idea for their spouses or partners to also be checked. Whether or not the spouse is diagnosed, prevention is important and changing lifestyle habits is easier if both partners are involved. [BMC Medicine, January 2014]





## SNIPPETS

### Health spending

Research in the US has shown that 91% of the annual healthcare costs were due to the prices of drugs, devices and hospital care and not the growing population of elderly patients. The study also showed that chronic conditions in people under 65 years were responsible for two thirds of the total US healthcare spending. How much does this apply to the UK?

### 'Action on Sugar'

This is a new group formed by health experts from around the world to reduce the amount of sugar added to processed foods and soft drinks. A reduction of 20 – 30% of added sugar which is about 100kcal per day could reduce or halt the obesity epidemic.

### GP changes name in protest over funding

GP Dr John Cormack from Essex has changed his name by deed poll to 'Dr John Cormack – the family doctor who works for the NHS for free'. He believes that his 4,000 patient practice is the worst funded in Britain. He says that he has tried every sensible way of raising this matter but has got nowhere. He has now launched an appeal for more funding after a meeting with his MP and the NHS.

### NHS patients going blind unnecessarily

The Independent Newspaper [14.11.13] reported that a survey by the Royal National Institute for the Blind [RNIB] found that NHS patients are going blind from avoidable conditions because eye clinics are delaying treatment and follow-up care caused by being too busy.

More than 80% of the 172 ophthalmologists and nurses who responded to the survey said that their clinics did not have sufficient capacity to meet demand. As a result, people are losing their sight unnecessarily. The RNIB has called for the health service to conduct an urgent inquiry into the quality of eye care services and recommended that NHS England create a post for a national clinical director for eye care provision to oversee services.

### Melbourne Declaration on Diabetes

The first meeting of the Global Parliamentary Champions for Diabetes Forum was held in Melbourne from 30th November

to 2nd December 2013 and was attended by parliamentarians from over 50 countries. Ninety nations have now signed the Melbourne Declaration on Diabetes which advocates halting the rise in diabetes and obesity by 2025. It is estimated that there will be 382 million people with diabetes which will rise to 592 million by 2035 and 80% of people with diabetes live in low and middle-income countries.

### Breath testing for blood glucose monitoring

Researchers in the US have developed a breathalyser-type device for monitoring blood glucose which is non-invasive. The device is still in the early stages of development, one of the problems being that it is too large. Clinical trials are planned for late 2014/15 when the device will be tested against standard finger pricks tests. They will also be looking for other things that could interfere with testing the breath, such as smoking, types of food eaten and testing time from eating or drinking. [Research presented at the American Association of Pharmaceutical Scientists meeting 2013]

### Women and heart attack myth exploded

Research has shown that it is a misconception that heart disease is more of a problem in men than women. The findings show that women between the ages of 18 and 55 have more medical problems, more chest pain and poorer quality of life before their heart attacks compared to men in the same age group. Women also were more likely to be obese and have a history of stroke or diabetes. The British Heart Foundation say, 'Heart diseases can be a lonely and challenging experience for many women and the sooner we explode the myth that it's a male preserve, the better.' [The Virgo Study, the Quality of Care and Outcomes Research 2013 Scientific Sessions]

### From your editor – Jenny Hirst

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