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ABCD Newsletter

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EDITORIAL

Time to stand up?

Mark Savage
Editor, ABCD newsletter

NICE in 2009 in their clinical guidance on the management of Type 2 Diabetes looked at the evidence for the use of basal analogue insulins and intermediate human insulins such as Insulatard, Insuman and Humulin I; their conclusion was that whilst there are clear conditions when the basal analogue insulins should be used the default starting insulin should be one of the human intermediate insulins.

Despite the coalition government promising to "ring fence" the NHS budget and to avoid cuts in the NHS, we are all aware that financial strain continues to be a major problem and indeed real cuts are an every day occurrence. The reasons for this are complicated but would appear to essentially boil down to too much demand and the health care inflation rate being greater than the general inflation rate. Thus, the tendency of Diabetes Nurses and Diabetes Doctors to prescribe basal analogue insulins as a default reflex action in many cases has been put under the spotlight as increasingly prescribing leads in commissioning groups (at least in England) are becoming increasingly aware that human intermediate acting insulins are approximately 50% of the cost of the available analogue basal insulins. This has lead to increasing pressure on Diabetes Units to move entirely to human intermediate acting insulins rather than use basal analogue insulins in several areas of the country. What are ABCD to make of this?

An ABCD position statement has been drawn up by Patrick Sharp and makes the point that there should not be any sudden changes in prescribing policy as this will put patients at risk. ABCD however does recognise the logic behind the original recommendations from NICE. ABCD's position statement is published in full on page 6 of this newsletter.

Taking up the point made by Chris Walton in his Chairman's report, commissioners do need the specialist input and this is another example of the need for commissioners who are responsible for diabetes services to engage with Diabetologists. Often the commissioners do not engage and that therefore puts the onus on us as representatives of our patients' interests to be pro-active, ideally through local diabetes networks and contacts.

INSIDE

DVLA seeks help from ABCD members

The European Union's recent directive on minimum standard for driving standards for diabetes has significant impact on people with diabetes and for those charged with advising the DVLA through assessment. This issue has been given a very high profile as a result of the Prime Minister's questioning on why the EU was issuing such directives and whether other governments were also 'trying to get those diabetics off the road'. This somewhat inflammatory statement has raised great concern among people with diabetes who fear that they will now be unable to drive, with speculation that up to one million people with diabetes will loose their license. As is usually the case in such matters, the changes required are not as major as initially presented, and are very much dependent on the sense and expertise of diabetes specialists.

The Prime Minister also urged that UK government departments did not 'copper plate' new EU regulations, as has frequently been the practice in the past. This is a view firmly held by those of us on the driving standards advisory panel for diabetes. At our recent panel meeting for diabetes, I took the opportunity to clarify some issues concerning assessment for Group 1 (diab3) assessments.

The most important change is that where a patient has had two episodes of hypoglycaemia requiring assistance from a third party at anytime (including when sleeping) in a year, they must inform DVLA. The requirement of assistance would include admission to A and E, treatment from paramedics, or from a partner/friend who has to administer glucagon or glucose because the patient cannot do so themselves. It does not include a third party offering assistance, but the patient not requiring it. It follows that when filling in the questionnaire that great care is taken to elicit exact history of each episode, and it would be sensible to chart this information carefully in the notes. Where two definite episodes are found the doctor must inform the patient that they need to tell the DVLA, and it again would be sensible to chart that advice.

In some cases, it may be suspected that severe nocturnal hypoglycaemia is present in a patient sleeping on their own, but when not witnessed, this would not constitute an episode for reporting. So, paradoxically, people sleeping on their own, with nocturnal hypoglycaemia may be advantaged in terms of maintaining their driving license, although clearly not in terms of overall well-being. Also biochemical or CGMS evidence of hypoglycaemia does not constitute evidence to stop driving in the absence of symptoms.

Unfortunately severe hypoglycaemia during pregnancy is counted in the same way, even though these episodes tend to be concentrated during the early part of pregnancy.

Some people will not inform the DVLA of this change in medical status. When a doctor is aware that a patient has been advised to stop driving yet continues to do so, and who has sought the assistance of family to ensure reporting, then according to GMC advice, the medical advisor to the DVLA should be informed, telling the patient that this is being done. It is up to the DVLA to revoke/renew the license. However, it should be noted that only 112 licenses were revoked last year.

A further change in the regulations enables insulin treated diabetes to apply for Group 2 driver permission. Group 2 vehicles originally called HGVs (Heavy Goods Vehicles) and PSVs (Public Service Vehicles) are now classified as Large Goods Vehicles (LGV) and Passenger Carrying Vehicles (PCV). These are vehicles in excess of 7.5 metric tonnes laden weight or minibuses with more than eight seats if driven for hire or reward. The DVLA is seeking a network of diabetes assessors to help with these applications, and is seeking ABCD assistance in this programme. There are issues to be resolved which include how the assessors are to be selected. Highly experienced specialist diabetologists with detailed understanding of the nature and implication of hypoglycaemia and unawareness thereof will be needed. Standards for assessment and training standards will need to be set.

Finally the implications for indemnity insurance such as MDU/MPS need to be clarified. A rapid task and finish group to establish best practice for Class 2 assessment (which is likely to be required as early as November) is being established, and Michael Feher has agreed to chair this group.

I hope that you will find these comments more useful than the Prime Minister's recent statements, this issue is important for people with diabetes and deserves better than a throwaway gag at the party conference.

Ian Gallen

Call for ABCD members to volunteer for the SCE Question-Writing Group

ABCD and the Society of Endocrinology are the two professional bodies whose members contribute to the SCE Question-Writing Group (SCE-QWG).

In order to ensure the high standard of questions for the Diabetes and Endocrinology SCE continues, the Examining Board wish to invite members of ABCD to volunteer to serve on this group to replace retiring members and bring new blood and ideas to the group.

Two meetings are usually held per year and full training in question writing is provided by the Royal Colleges of Physicians.

Eligible candidates will be those who have already taken and passed the SCE examination or those who are established consultants who are not permitted to do so.

If you are interested please contact Dr Mark W Savage at mark.savage@pat.nhs.uk

A report from the Association of British Clinical Diabetologists (ABCD) Spring Meeting

Hilton Birmingham Metropole, 6 May 2011

Impact of NHS changes on delivery of care

The NHS is going through a period of rapid change and two speakers presented models of care at this year's ABCD Spring Meeting in Birmingham. On the opening evening, the invited guest lecturer, Steve Laitner (NHS East of England) described the prime contractor model for delivering integrated care in the East of England. He explained why the system has to change; at the moment it is too hospital based and paternalistic; furthermore demand is rising at a time of an unprecedented reduction in resources.

Dr Laitner explained how NHS East of England is to help GP consortia commission a new model to join up services – an integrated pathway hub (IPH) delivered by a prime contractor. In the new model a single provider will be given the total budget for a programme, and will be accountable for the quality and cost of the entire patient pathway across primary, community and acute care. The prime contractor will provide part of the care pathway – community-based specialist services as an alternative to hospital outpatients as well as managing the rest of the pathway through subcontractors. Unlike the current model the new integrated pathway hub would not be affected by PBR and would have a population based budget. But there would be PBR for subcontractors.

During the course of the following day, Dinesh Nagi (Pinderfields General Hospital, Wakefield) explained the redesign of the diabetes service in the Wakefield area. The new service should provide structured and organised care, should be easily accessible, address health inequalities, reduce variation across practices and, most importantly, integrate primary and specialist care. It should not lose patient focus, and create a model with a large extra drain on resources. Following a number of meetings starting in 2006 a model based on patient focus groups and the views of the healthcare community, was presented. A diabetologist and DSN would be attached to a practice. The DSN would work jointly with the practice nurse. Where required, patient consultation would be with the GP and diabetologist together (led by the GP but with an emphasis on the patient being "in charge". And a clear, agreed and documented plan of action would always be produced.

Dr Nagi anticipated that there would be increased carer and patient satisfaction. Benefits to people with diabetes would include swift referral to the specialist team if required and prompt intervention; and a structured education programmes being delivered in their locality. Other benefits include the elimination in the duplication of diabetes care by primary and specialist care and increased understanding of both their roles.

Insulin pump therapy in diabetes

Stephanie Amiel (King's College London) updated delegates on the latest developments in insulin pump therapy. NICE has calculated that 15% of patients should be receiving CSII but less than 5% of type 1 patients in the UK are so doing (the lowest level in Western Europe). So although many doctors are reluctant to commence CSII, and although, of course, it is not a cure for diabetes, it has advantages. It has been shown to reduce hypoglycaemia problems and improve overnight control (especially the dawn phenomena) in appropriate individuals. And, Professor Amiel produced evidence from studies showing that many patients like the positive effects that pumps have had on their lives.

NICE now recommends that CSII should be considered in patients currently on MDI if attempts to achieve target HbA1c without disabling hypoglycaemia fail, or where HbA1c remains at 8.5% or more, despite a high level of care. She discussed the advantages and disadvantages of real time glucose monitoring, the closed loop and the bolus calculator. Professor Amiel offered advice on what to do if CSII did not deliver and suggested that perhaps 20% of patients should be receiving pump therapy.

Sulfonylurea-induced hypoglycaemia

Brian Frier (Royal Infirmary, Edinburgh) reminded delegates that hypoglycaemia is a recognised side-effect of sulfonylurea therapy but, he asked, is this significant problem? Professor Frier pointed out that hypoglycaemia and asymptomatic hypoglycaemia in type 2 diabetes are often undetected and unrecognised, particularly in primary care. It is associated with type 1 diabetes; patients are ill-informed about the symptoms, enquiry is seldom made about it at routine diabetes consultations and its manifestations may be attributed to other medical disorders.

Sulfonylureas have been used in type 2 diabetes for more than 50 years; they are cheap, have a rapid onset of action and although they cause weight gain, this is seldom excessive. And there is no good evidence for adverse cardiovascular effects. The frequency of hypoglycaemia with sulfonyureas is equivalent to that observed with early insulin treatment, it is more likely to occur within the first month of treatment and is more common when patients are treated with low doses or with long-acting preparations. The risk factors for severe hypoglycaemia include age and Professor Frier suggested that in older people, short acting preparations should be used.

Diabetologists as endocrinologists

Andrew Hattersley (Peninsula Medical School, Exeter) presented the case for endogenous insulin secretion as a guide to therapeutic decisions. The thrust of Professor Hattersley's argument is that, while there are clear guidelines for treating diabetes, its classification into types 1, 2 and subtypes is not based on defined clinical criteria. And yet, as he illustrated through examples, classification matters because it impacts on treatment and initial assessments can be wrong. He suggested that diabetologists should now embrace an endocrinological approach. One such method is to measure endogenous beta-cell function in people on insulin, and Professor Hattersley put forward the case for the urinary C peptide creatinine ratio measurement. This can determine if patients with type 1 or 2

diabetes are producing their own insulin. It can also be used to differentiate type 1 from type 2 diabetes, as well as the subtypes. It can replace multiple blood tests and can be sent through the mail as it is stable for up to three days at room temperature. Whilst expert and careful interpretation is needed, the test is inexpensive (£10) and is available through the Royal Devon and Exeter Biochemistry laboratory.

Quiz the experts – insulin and cancer

As a change from the traditional ABCD debate, there was a Quiz the Experts session. The subject for the first of these was insulin and cancer and the experts were Andrew Renehan (The Christie NHS Foundation Trust, Manchester) and David Russell-Jones (University of Surrey, Guildford). Professor Renehan explained how diabetes, obesity and cancer are linked through the insulin-IGF axis. Circulating total IGF-I and IGFBP-3 are associated with cancer risk; however, IGF-I in cancer biology is complex and goes beyond mitogenicity. Both obesity and diabetes has been associated with the risk of several cancer types – in the latter case, this can be independent of BMI. Insulins may increase cancer risk whilst metformin may reduce it.

Professor Russell-Jones reminded delegates of the history of Novo Nordisk's X10 experimental rapid-acting insulin analogue, which had been shown to be mitogenetic. He emphasised that in the development of new insulins, it will be necessary to investigate their binding characteristics. Increased IGF-1R affinity and increased duration of activation of IR can be tested in preclinical development, but, he stressed, correct methodology is critical to avoid misleading data.

The importance of this topic was underlined during the lively pro-active session when both speakers answered a number of questions. Asked about the numbers needed to show mitogenetic problems with existing insulins, Professor Russell-Jones said that it depended on the study used but that more clarification should be available next year. And there was much discussion on pro-insulins. Offering advice to be given to patients, Professor Renehan suggested that in diabetic patients without cancer, the message should be one of reassurance regarding existing insulin analogues. In diabetic patients with cancer, medications and risk factors should be reviewed regularly. And non diabetic cancer patients should be encouraged to participate in metformin adjuvant trials.

Endocrine topics

Neil Gittoes (Queen Elizabeth Hospital Birmingham) offered useful advice on the management of hypocalcaemia. Clinical symptoms include neuromuscular hyperexcitability, paraesthesiae, cramps/twitching, carpopedal spasm and tetany, seizures and arrhythmias. Whilst hypocalcaemia is the presence of low serum calcium, the rate of change is more important than absolute values, he emphasised. Investigations should start with PTH: if low or normal, magnesium; if high, urea and creatinine. Dr Gittoes discussed the relationships between low serum calcium/phosphorus, osteomalacia/rickets (on the increase) and vitamin D deficiency. Sunlight is the main source of vitamin D synthesis and a small area of exposure three times per week for 10 to 15 minutes in summer is more important than diet. Most oral vitamin D2 or D3 supplements include calcium. Small doses produce a slow and variable response but large (pharmacological) doses produce a rapid and reliable response. Dr Gittoes then used some case histories to illustrate the management of hypocalcaemia following neck surgery, hungry bone syndrome and hypomagnesaemia. Mark Gunnel (Addenbrookes Hospital, Cambridge) also used case histories to explain the investigation and management of hyperthyroxinaemia with non-suppressed TSH. Dr Gunnel suggested an algorithm in order to differentiate between TSH-secreting pituitary adenoma and resistance to thyroid hormone.

Charles D Wroe, Medical Correspondent

Joint Meeting of the Association of British Clinical Diabetologists and the Renal Association

Diabetes and Kidney Disease: Advances and Controversies

23 February 2012, International Convention Centre, Birmingham

9.50	**Introduction and welcome**
10.00	**Tubular disease in diabetic nephropathy: long term data and insights from proteomics** Professor Peter Rossing, Steno Diabetes Center, Denmark
10.45	**New therapies for diabetes and their use in kidney disease** Professor John Wilding, University Hospital Aintree, Liverpool
11.45	**Renal denervation for refractory hypertension** Dr Mel Lobo, Barts and the London Hospital Trust
14.00	**Mineral bone disease and vascular calcification in diabetes and kidney disease** Professor John Cunningham, Royal Free Hospital, London
14.45	**Preventing amputations in people with diabetes and kidney disease** Dr Fran Game, Royal Derby Hospital
15,45	**New onset diabetes after transplantation: a non-modifiable risk factor for cardiovascular disease post-transplant** Dr Richard Smith, Bristol Southmead Hospital
16.15	**Summary and close**

For further details and to register contact Elise Harvey tel: 01666 840589, email: eliseharvey@redhotirons.com or visit: www.diabetologists-abcd.org.uk. There is a reduced registration fee for booking before 9th January 2012.

Chairman's report

Reasons to be cheerful part 3

As I pick up the reins from Peter Winocour and survey the diabetes landscape I ask myself if even Ian Drury could have found reasons to be cheerful. The reasons to despair are legion. Financial constraints threatening to erode gains in diabetes care (where gains have occurred) or to destabilise already tottering diabetes ecosystems. People with diabetes denied access to specialist opinion because of perverse incentives, such as Payment By Results, with new to follow up ratios unthinkingly applied. More stringent driving regulations arising from European Law which, despite best efforts at mitigation by the Department of Transport Medical Advisory Committee, have made life significantly tougher for patients, and arguably in the case of nocturnal hypoglycaemia, without a basis of solid science. Trusts flailing in the deep water, trying not to be the first to drown and losing interest in anything which is perceived as not a big earner. Lord Crisp citing diabetes as an example when saying we have too many consultants and nurses can do all the work. Trainees so overloaded with acute medical commitments that they lack the time to engage with developing areas such as community care. Ditto consultants, the list is endless.

Hope springs eternal

However arguably the human race survives because of (often unreasonable) optimism and when I get out of bed in a morning I am not short of reasons to be cheerful. Like the economy the progress of diabetes care is cyclical. The darkest hour precedes the dawn with remarkable regularity and like investors who invest at the point of maximum pessimism, commissioners who invest wisely in quality models of care can expect to reap dividends for patients. While conferring wisdom on commissioners is beyond our control (unless more of us become commissioners) our role is to relentlessly educate them and to create, provide and promote affordable, quality models. As experts in behaviour change surely we can change our behaviour sufficiently to survive the buffeting of the recession and thrive? If the diabetes epidemic doesn't ensure that specialists in managing this often complex disease flourish then what will? We must be determined and patient preparing for the opportunities which will come.

Strength in our skills

Indeed there is ample evidence that diabetologists are creating new constructs and models of care with a combination of the enterprise and pragmatism that diabetologists have always shown. As a charity and an Association purely of volunteers our members are our main assets and the vibrancy of thought and action is apparent not least in younger committee members such as Niru Goenka, Partha Kar and Emma Wilmot.

Strength in collaboration

The increasing strength ABCD's relationships with other organisations and the number of collaborative projects is another cause for optimism.

This is exemplified by:

1. The Joint British Diabetes Societies In-Patient Group whose funding into the future is agreed in partnership between ABCD and Diabetes UK, and which is going from strength to strength under the able chairmanship of Mike Sampson. Workstreams with outputs planned include enteral feeding, e-learning, hyper and hypoglycaemia, admissions avoidance and self management. The Titan ACS * project which was funded jointly through NHS Diabetes and ABCD set out to show the safety and efficacy of the insulin infusion regime in coronary care units and Maggie Hammersley is preparing reports on its outcomes.

2. Diabetes UK's willingness to be co-signatories to the ABCD created letter on Pioglitazone to the European Medicines Authority.

3. The National CSII Audit which has been commissioned through ABCD on behalf of a consortium which includes Diabetes UK and JDRF (Ian Gallen leads the steering group for this project).

I recently attended the first programme board of the National Diabetes Audit, the governance of which has now been taken on by Diabetes UK, and was genuinely excited. This collection of national audits will assume increasing importance in the years to come and diabetologists have a vital role to play in translating the figures and statistics into outputs of value to people with diabetes and local diabetes care communities.

The nationwide audit programme led by Bob Ryder is also flourishing and new developments include the possibility of moving the audit tool within an NHS.net environment for future audits of new agents. By allowing retention of the NHS number this opens up exciting possibilities for data linkage. Bob's other key role is as website officer and he has now set up a website board to supervise an extensive revamp of the website; the fruits of these labours will become apparent over the months to come.

As chair of ABCD I am conscious of the need to work closely with the National Clinical Director Rowan Hillson and support the admirable work for which she and Gerry Rayman and others have been responsible, within the area of inpatient care.

ABCD continues to support the developmental needs of trainees with the Kings Fund course and to discuss and develop common initiatives with YDF. In addition, I have a strong wish to engage with the Primary Care Diabetes Society to ensure that they are at the table to bring the primary care perspective into the many areas of common interest.

The new executive and committee

Thanks must be expressed to Peter Winocour for his tireless and productive work as Chair and Secretary, and for ensuring a smooth transition; his continuing presence within the executive group as immediate past chair is a source of stability at a time of much change.

Thanks also to the departing executives Ian Gallen and Dinesh Nagi and welcome to the new executives, Patrick Sharp (General Secretary), Rob Gregory (Treasurer), and

Ketan Dhatariya (Meetings secretary). Dinesh and Ian are continuing to be active within ABCD leading on the manpower survey and the CSII audit respectively.

Among departing committee members particular thanks are due to Anne Kilvert who has selflessly been involved in so many committee initiatives over the years and has recently represented ABCD in discussions with the NPSA over the insulin passport, and to Nick Morrish who after years of toil collecting manpower data has handed over the manpower survey (jointly funded by ABCD and Diabetes UK) to Dinesh Nagi.

ABCD will continue to support high quality diabetes care across the four nations and I welcome the new committee representatives from Northern Ireland (Hamish Courtney), and Wales (Aled Roberts). Johnny McKnight continues as Scottish Representative.

A warm welcome to our other new committee members Daniel Cuthbertson, Russel Drummond, Dipesh Patel, Tony Robinson, Dev Singh, and Jonathan Valabhji.

Conclusion

As ABCD, a relatively small society with limited means but growing activity, we must seek to catalyse change by influence and working collaboratively, achieving change while preserving that which is good.

As diabetologists we must align ourselves with, and focus on, the needs of people with diabetes; their needs are great at a time when political whim and false perception threaten to fragment the care pathway. We must seek to understand and influence the forces which are driving sometimes irrational changes in our local and national care systems. If we do this we will not go far wrong and perhaps end up just a tad more cheerful!

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Chris Walton

ABCD Position Statement: Analogue Insulins

ABCD welcomes the publication of Holden et al (BMJ Open 2011;**1**:e000258 doi10.1136/bmjopen-2011-000258) although with some caveats. Holden's analysis estimates the additional cost to the NHS of the use of analogue insulins rather than human insulin. Whilst the advantages of analogue insulins in terms of their more physiological profiles should not be forgotten, at a time when financial considerations are at their most pressing, a reminder of the cost implications of our clinical practice is appropriate.

Insulin was originally extracted from animal pancreas, but the introduction of synthetic insulin in the early 1980s opened the way for the production of human insulin. It was a logical progression, therefore, to analogues of insulin, initially with a more rapid onset of action and subsequently to longer acting analogues of insulin. An assessment of the clinical and cost effectiveness of the insulin analogues has been included in major clinical guidelines, most notably those issued by NICE for the management of type 1 and type 2 diabetes (CGs 15 and 66) and SIGN guideline 116. The practicalities of the short duration of action of rapid acting analogues and single daily dosing regimen of longer acting analogues were noted together with limited evidence for a reduction of hypoglycaemia with these agents. The published guidance is consistent in recommending human insulin as first line therapy with consideration of analogues in certain circumstances.

These circumstances include the use of long acting analogues where an individual needs external help to administer insulin or has suffered troublesome nocturnal hypoglycaemia. Rapid acting analogues could be considered where injection immediately before food is preferred and where there are marked postprandial glucose excursions with human soluble insulin. For those individuals treated with a basal bolus insulin regimen, therefore, rapid acting analogues will remain the treatment of choice.

Since their launch, there has been an increase in the use of analogue insulins to the point where their use may not be supported by published guidance in some instances. The value of the report of Holden et al. lies in the attention it focuses on the cost of use of analogue insulins in preference to human insulins. The authors discuss the limitations of their report. They comment on the assumptions used to reach their conclusions and likewise comment on the impracticality of replacing all prescriptions for analogue insulin with a human insulin preparation. Nevertheless, the point should be well taken: there is a cost associated with the use of such preparations.

While valuable, this report should not prompt any sudden changes in prescribing policy: many patients are well controlled on analogue insulin, and their treatment should not be changed in response to this analysis. The major clinical guidelines for diabetes leave the option of use of analogue insulin to the clinical judgement of the clinician and this report should not change that position. Nevertheless, the reported figures should act as a timely reminder that we should consider, with each prescription, precisely why it is judged that an insulin analogue will offer benefit over and above that conferred by a less costly human insulin.

ABCD welcomes innovative treatments for diabetes, including new insulins that offer those patients who are experiencing problems with established treatments the prospect of better control with fewer problems. However, the Association supports a view that prescription of analogues of insulin should be considered only when the use of human insulin has been considered and rejected.

Declaration of interest:

ABCD (Diabetes Care) Limited receives financial support from Lilly, NovoNordisk and Sanofi-Aventis, all of whom manufacture analogue insulins that are available in the NHS.