### Clinical DIGEST 7

#### **Paediatrics**

# PAEDIATRIC NURSING

# Trial involvement improves self-management

Readability	<b>///</b>
Applicability to practice	1111
WOW! factor	1111

The researchers hypothesised that participation in a clinical trial would have a positive effect on the education and management of diabetes in people between the ages of 6 and 17 years.

Children and young people in the UK and Ireland with type 1 diabetes (n=44) were asked to complete a questionnaire based on their experience of exposure to intensified intervention during a clinical trial that compared specific insulin regimens.

During the research period, most individuals were obliged to increase their injection frequency, clinic attendance, glucose monitoring and diary entries.

The questionnaire was completed by 36 of the 44 (81.8%) individuals.

Most of the respondents did not express concern about basal—bolus therapy, additional injections or intensified self-monitoring: in total, 97% indicated that they intended to continue with multiple daily injection therapy and 67% reported that they would continue to test their blood glucose as frequently after the trial.

In addition, 56% of individuals said they had improved knowledge and understanding of diabetes as a result of the trial and 86% agreed that an increase in clinic visits was beneficial.

This study demonstrates an improvement in diabetes management as a result of increased contact with professionals and intensive insulin management.

McGuinness C, Cain M (2007) Participation in a clinical trial: views of children and young people with diabetes. *Paediatric Nursing* **19**: 37–9

## Participation in a clinical trial: views of children and young people with diabetes



Krystyna Matyka, Senior Lecturer in Paediatrics, University of Warwick Medical School any medications prescribed in the paediatric population are unlicensed in young children and their use is almost always based on best clinical practice rather than sound research data from randomised controlled trials (RCTs). This has

the disadvantage that their effectiveness has not been rigorously tested and, instead, findings from adult research studies are extrapolated to underpin drug use in children. It is on this background that the National Institute for Health Research (NIHR) Medicines for Children Research Network (MCRN) has been created to 'improve the co-ordination, speed and quality of RCTs and other well-designed studies of medicines for children and adolescents, including those for prevention, diagnosis and treatment.' (www.mcm.org.uk [accessed 01.11.07]). Such a network is necessary since good-quality RCTs normally require the recruitment of a significant number of research participants and this involves multicentre participation.

Part of the vision of the MCRN is that they will be informed by the views and perspectives of children and families, and the involvement of 'user' groups in the development of research protocols is encouraged by many funding bodies as good practice. The benefits to individuals from taking an

active part in research are less clear. The paper to the left by McGuiness and Cain suggests that the benefits of research participation may be greater than we think. This paper describes the experiences of a group of children and adolescents who took part in a multicentre international study to compare two different background insulins used as part of a basalbolus insulin regimen. The study was small with only 36 children taking part from one research centre; yet, of these, 56 % felt that their diabetes knowledge was increased through study participation (although this assumption was not tested). This knowledge included a greater understanding of HbA<sub>1,c</sub>, blood glucose control and insulin dose adjustment. In total, 86 % of children expressed satisfaction with increased clinic visits and telephone contact. Although people who take part in research studies may not be entirely representative of all patients attending clinical services, it would appear that engagement with a research study did bring some extra benefits to the research participants themselves.

There are obviously a number of ethical considerations in performing interventional research studies in young children and the risk—benefit ratio needs careful deliberation. However, with better clinical trials providing more robust data on the optimum management of childhood diabetes, it is hoped that the clinical care of these young people may be improved — and this study suggests that young people may benefit in the short term as well.

#### **DIABETES CARE**



# Extensive TV watching compromises blood qlucose control

At baseline, the mean age of the 538 children who participated in this study was  $13.1 \pm 3.7$  years; the mean duration of diabetes was  $5.4 \pm 3.4$  years; and the mean HbA<sub>1c</sub> was  $8.6 \pm 1.3$  %. The children all had type 1 diabetes and were on record at nine hospitals in Eastern Norway.

The time spent watching TV and using a computer was recorded separately.

TV was watched daily for <1 hour by 62 (11 %) individuals (mean HbA<sub>1c</sub>:  $8.2\pm0.9$  %), 1–2 hours by 189 (35 %) individuals ( $8.4\pm1.2$  %), 2–3 hours by 166 (31 %) individuals ( $8.7\pm1.4$  %), 3–4 hours by 75 (14 %) individuals ( $8.8\pm1.2$  %) and  $\geq4$  hours by 46 (9 %) individuals ( $9.5\pm1.6$  %).

This association between TV watching and  $HbA_{1c}$  (P<0.001) remained significant after adjusting for BMI and insulin dose. There was no association between computer use and  $HbA_{1c}$ .

Margeirsdottir HD, Larsen JR, Brunborg C et al (2007) Strong association between time watching television and blood glucose control in children and adolescents with type 1 diabetes. *Diabetes Care* **30**: 1567–70

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Quality-oflife scales for
mental health,
symptoms, health
status, cognitive
functioning
and adherence
barriers during
treatment all
favour inhaled
insulin over
subcutaneous
injection.

### DIABETES CARE

#### High risk of cardiometabolic abnormalities in Southern Indian teenagers

Readability	////
Applicability to practice	1111
WOW! factor	1111

- This study involved 2640 teenagers (1323 boys and 1317 girls) aged 12–19 years from various socioeconomic backgrounds in Southern India.
- Demographic, social and medical details were recorded, and anthropometry and blood pressure were measured, along with fasting plasma glucose, insulin and lipid profiles.
- Factor analysis was used to identify clusters of risk variables, and the association between individual risk variables and their clusters, and insulin resistance was assessed.
- In total, 67.7 % of the children (64.8 % of normal weight and 85 % of overweight children according to BMI) had at least one cardiometabolic abnormality (low HDL-c or elevated triglycerides, fasting plasma glucose or blood pressure).
- Each of the above abnormalities was associated with insulin resistance apart from HDL-c.
- Insulin resistance was also associated with BMI, waist circumference, body fat percentage and total cholesterol (*P*<0.0001).
- Three distinct clusters of risk factors were identified: waist circumference and blood pressure; dyslipidemia, waist circumference and insulin; and waist circumference, glucose and plasma insulin.
- The authors concluded that there is a high incidence of cardiomatabolic abnormalities in healthy Asian—Indian adolescents and insulin resistance is associated with individual cardiometabolic risk factors

Ramachandran A, Snehalatha C, Yamuna A et al (2007) Insulin resistance and clustering of cardiometabolic risk factors in urban teenagers in southern India. *Diabetes Care* **30**: 1828–33

### INTENSIVE CARE MEDICINE

#### SC insulin glargine speeds up resolution of DKA

Readability	1111
Applicability to practice	////
WOW! factor	1111

A retrospective cohort study compared the ability of SC insulin glargine (0.3 units/kg in the first 6 hours of management) plus standard treatment (n = 12) with that of standard treatment alone (n = 59) to resolve moderate to severe diabetic ketoacidosis (DKA) in children.

- Acidosis correction (venous pH  $\ge$  7.3) took 12.4 hours in the insulin glargine group, compared with 17.1 hours for controls (P< 0.001).
- In addition, the insulin infusion time was shorter with insulin glargine (14.8 vs 24.4 hours; P<0.001) and there was a trend towards shorter hospital stay (a mean of 3.2 days compared with 3.72 for controls).
- In conclusion, supplementing with SC insulin glargine leads to faster resolution of DKA with no side effects. This could potentially reduce insulin infusion time and ICU length of stay.

Shankar V, Haque A, Churchwell KB, Russell W (2007) Insulin glargine supplementation during early management phase of diabetic ketoacidosis in children. *Intensive Care Medicine* **33**: 1173–8

### DIABETES CARE

## Better adherence with inhaled than injected insulin

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Readability	111
Applicability to practice	1111
WOW! factor	1111

- The impact of inhaled versus injected insulin was measured in adolescents (12–17 years) and adults with type 1 diabetes who received premeal subcutaneous plus twice-daily NPH insulin during a 4-week run-in.
- Participants were then randomised to continue this therapy (105 adults; 60

adolescents) or switch to inhaled premeal insulin (102 adults; 60 adolescents).

- Treatment satisfaction, measured on a scale of 1–100, increased by 13.2 for inhaled insulin compared with 1.7 for injected (P<0.0001). All 12 satisfaction subscales favoured inhaled insulin, irrespective of age or sex.
- HbA $_{1c}$  was similar for inhaled (7.7%) and subcutaneous (7.9%) regimens; however, quality-of-life scales for mental health, symptoms, health status, cognitive functioning and adherence barriers during treatment all favoured inhaled insulin significantly (all P<0.05).

Testa MA, Simonson DC (2007) Satisfaction and quality of life with premeal inhaled versus injected insulin in adolescents and adults with type 1 diabetes. *Diabetes Care* **30**: 1399–405

#### JOURNAL OF PAEDIATRIC ENDOCRINOLOGY & METABOLISM

## **Criteria for OGTT testing in youths**

Readability	///
Applicability to practice	11
WOW! factor	11

- This study identified criteria that predict an abnormal OGTT in obese youths at risk of developing type 2 diabetes.
- Algorithms that yielded 100 % sensitivity when predicting an

abnormal OGTT were derived to identify those individuals who should be screened for diabetes

- Girls who met this criteria had HOMA > 4.5 (specificity: 53.7 %).
- Boys who met this criteria had HOMA > 13,  $HbA_{lc} > 5.8$ % or total cholesterol > 200 mg/dl (specificity: 76.6%).
- A large patient sample yielded similar results and validated this model.
- These criteria identify individuals at risk of diabetes who should undergo OGTT.

Puri M, Freeman K, Garcia M et al (2007) Criteria for oral glucose tolerance testing of obese minority youth. Journal of Paediatric Endocrinology & Metabolism 20: 703–9

There is a high incidence of cardiometabolic abnormalities in healthy Asian–Indian adolescents.