



Improving Children's Health Through the Delivery of NIHR Portfolio Studies - The BEAGLE Study

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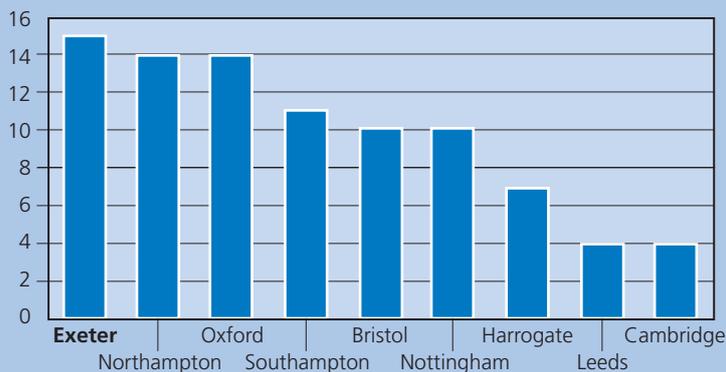
Background

The Beagle Study aimed to demonstrate the accuracy of the Abbott Sensor Based Glucose Monitoring System versus finger stick blood glucose readings in children aged 4-17 with type 1 diabetes on insulin therapy (either subcutaneous injection or continuous glucose device usage).

Sensor is already licensed in adults aged over 18 years but no child trials have been done.

Method

- Children wore a sensor on the back of the arm for up to 14 days.
- The study involved 3 visits and 1 telephone call.
- Patients were asked to perform a minimum of 4 capillary Blood Glucose tests a day, immediately followed by a sensor scan.
- Sensor data was masked to the subjects until the final clinic visit where the device was unmasked for patients and parents to experience full functionality.
- 89 paediatric subjects were recruited from 9 hospitals between March 2015 and end of May 2015.
- Recruitment was competitive. In Exeter we had an initial target of 10, however we managed to recruit 15 subjects making us the highest recruiting site in the UK.



Results

- Comparison between the blood glucose device system and capillary blood glucose indicate the device is accurate in the paediatric population.
- The number of device related adverse events was similar to that observed in the adult population, indicating the device is safe in the paediatric population.
- User satisfaction indicated a high level of acceptance of sensor wear and ease of use of the device.
- Device is now licenced in children. Company have given 1 device and 2 sensors to all children that took part in the Beagle Study.

How did we identify subjects?

- Following strong collaboration and support from the Paediatric Diabetes Specialist Nurses, Paediatric Dietician and Diabetes Doctors, an article about BEAGLE was put in the RD&E patient newsletter BiteSizE. This was posted out to all parents of child type 1 patients. A study flyer was also included to draw attention to the article. We timed the sending of the newsletter to coincide with R&DE approval.
- Research nurses set up a trolley with all research study information during outpatient diabetes clinics to talk to interested families.
- Word of mouth from Paediatric Diabetes Clinical Team.
- Local diabetes facebook group.

What approaches did we use that contributed to us being top recruiting site?

- Home visits for visit 2.
- After school visits.
- Saturday clinics.
- Telephone calls, at a time suitable for family.
- Take spare sensor to family instead of them needing to collect.



Conclusion

- This study was successful thanks to excellent team work and collaboration with the clinical diabetes staff.
- By research nurses working flexible hours at weekends and after school times to accommodate the needs of family life.
- By providing the option of a home visit at visit 2 to reduce the demands on families – 90% of parents took this up.
- By benefitting from research fellow input.

Improved quality and safety

- The licensing of this glucose sensor in children 4-17 years means improved quality of life for children with type 1 diabetes by reducing the number of finger prick tests required.
- Improved safety by parents being able to scan very young children through clothing especially at night without waking them up to check they are not going hypo whilst asleep.

