Diabetes research nursing

In this regular column, Shona Brearley discusses diabetes research nursing from a practical perspective, with the aim of sharing best practice ideas and giving readers the chance to ask for advice about their particular study. If you have any queries, or would like to contribute to this column, contact jdn@sbcommunicationsgroup.com.

Diabetes research in primary care: The need for a culture shift

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In my last column, I discussed the model behind our project to encourage diabetes research within primary care in Scotland. In this month's column, I will discuss the logistics behind this project and some of our preliminary results.

We originally had six GP practices registered but only three took part in the first study. The GP practices were a mixture of urban, suburban and rural practices and had scores of 2–10 on the Scottish Index of Multiple Deprivation (with 2 representing a very deprived population and 10 indicating an affluent population). The average diabetes population of each practice was approximately 300 people.

The first study that we conducted was a simple comparison of an immediate-release oral anti-diabetes drug with an extended-release formulation of the same drug in treatment-naïve people with type 2 diabetes. This study would have been difficult to conduct in secondary care as the eligible patient population was cared for entirely in primary care, so was unknown to the research team.

The diabetes specialist research nurse is assigned to the practice on one day a week and this often coincides with the practice diabetes clinic, which helps with the recruitment of participants. Potential study participants were first identified from the practice database as meeting all the eligibility criteria and then their suitability to take part in a clinical trial was discussed with their GP. Over the nine months that the project has been running, the research nurses have built up a close working relationship with the multidisciplinary team within the practice and are now seen as an integral part of the clinical care.

Engaging staff

The staff in the GP practice need to be engaged in any studies as their help is required for the daily tasks of running a study, such as temperature monitoring of sample freezers and drug cupboards, and reporting any abnormalities to the research nurse so that any necessary action can be taken. The practices involved in our initiative have also been very diligent in contacting the research nurse with notification of any adverse events. Furthermore, the receptionists at the practices have been invaluable in contacting the research nurse when the courier did not arrive to pick up the samples, or a refrigerated package of the trial drug arrived on a day when the research nurse is not present. Good communication among all staff members is essential so that supplies are stored safely.

The GP practices have all provided a consulting room for research participants' visits and storage space for all supplies. One of the GPs is also available each day to take informed consent, perform any physical examinations required and discuss any laboratory results or adverse events. The Scottish Diabetes Research Network (SDRN) provide all the clinical equipment that the practices need, such as centrifuges and –20°C freezers, and maintain the calibrations of this equipment.

If we want to conduct more research across the country, it is essential that we change the culture in both primary and secondary care, so that research is seen as part of routine care. I feel that we are certainly creating this culture in the GP practices that are currently hosting this initiative.

Preliminary results

Preliminary results from this project show that the GP practices are recruiting very well to their studies and are on track to hit their targets. Data quality is as good as in secondary care and the numbers of queries are minimal. The demographics of the practices appear to have had little impact on the numbers of people recruited, so it appears that the model can work in different populations and practice types. The numbers of patient visits that the research nurses are conducting is steadily increasing

Participants have reported that they are happy to take part in research in a primary care setting and benefit from extra time with a nurse.

each month, although with only one morning per week in each practice, and participants having to fast for all visits (for fasting plasma glucose tests), it is expected that numbers will plateau. However, some of the practices are now offering the project space on more than one morning per week, so hopefully we can continue to increase the numbers of people in studies.

Participant and research nurse satisfaction

Research participants seem to be happy taking part in the studies, especially as participation allows them extra tests. One individual who was screened for the trial was found to have paroxysmal atrial fibrillation, which was previously undiagnosed as he had no symptoms, and he was urgently referred to the local cardiology department for treatment. Other people who successfully completed the trial are delighted with their improved diabetes control and weight loss, and feel more empowered to deal with their diabetes on a day-to-day basis.

The diabetes specialist research nurses working on the project are enjoying educating both the trial participants and practice staff about diabetes research, and some practice nurses have shadowed the research nurses on a few occasions. Clinical research is being demystified and this can only increase uptake in the future.

The future

After a small pump-priming grant from the Chief Scientist Office of the Scottish Government, this project has to become financially viable and self-sustaining. Therefore, the business model, which disperses the per-participant fee paid by the sponsoring company, is critical to the future. Both parties, the GP practice and SDRN, are pleased with the income so far and we already have plans to increase both the number of participating GP practices and the amount of research nurse resource.

The sponsor of the first study conducted has already asked to open several more GP sites in Scotland and we are currently working with two more GP sites with the plan to have these practices running their first trial by the end of February 2015. We have several more studies wishing to start in 2015 and we now have a waiting list of GP practices who would like to host a research nurse and conduct diabetes clinical research.

We are currently developing an audit questionnaire for the practices to see how we could improve the model.

The future of this initiative looks promising with the possibility that we can significantly increase diabetes clinical research that is conducted entirely within the primary care setting. We believe that this model could be used for research into many conditions and we are already in negotiation with the Scottish Dementia Clinical Research Network as to how it could be used for their research. ■