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.

Logistics: The key to effective grants and successful research

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One factor critical to the success of a diabetes research study is feasibility. It is crucial that studies are placed in the right setting so that recruitment targets can be reached and study timelines adhered to. Investigators (usually physicians) can often be very enthusiastic about their research interests and it can be left to the research nurse to point out the logistics of why a study won't work.

When academic studies are being planned, and the protocol and grant applications being written, the research nurse who will be working on the study should collaborate with the investigator so that realistic recruitment and study timelines are developed. The research nurse should ask the following questions:

- Does the patient population actually exist?
- Does the protocol conform to current prescribing guidelines?
- Is the patient population easily accessible?
- How intrusive are all of the procedures?

As an example, several years ago, one Scottish Life Sciences colleague "promised" a company he would provide muscle biopsy tissue from people with type 2 diabetes patients who were on various oral hypoglycaemic agents (OHA) but no other drugs, without consulting the diabetes research team. However, as this was after publication of CARDS (Collaborative Atorvostatin Diabetes Study) and the EUCLID (Examining the Use of Ticagrelor in Peripheral Arterial Disease) study, which recommend a statin and an ACE inhibitor, respectively, in people with type 2 diabetes, only a handful of people fitted the criteria and it was impossible to reach the target number of tissue samples. Had he come to the research nurse before agreeing to a large number of these samples, he would have saved himself much embarrassment.

Any academic or commercial study must conform with the local prescribing practice if they are to be successful. People with diabetes today are all on a cocktail of drugs, which can make statistical analysis of trial results challenging. Ethically, many of these drugs cannot be removed just for trial purposes as the person's health may suffer, so the statisticians for clinical trials just have to learn to cope with these confounding factors. This leads us to the next question: "Is the required patient population accessible to the research team?" Increasingly, in trials, drug-naïve participants are being sought, which makes the hospital-based model of research very difficult, as these people are usually seen in primary care. Research registers, as have been previously discussed, can be useful here but this depends on the individuals being willing to come into secondary care to participate in research. The Scottish Diabetes Research Network has recently developed a primary care model whereby experienced diabetes specialist research nurses go into the community to conduct research solely in the primary care setting.

The time required by the research nurse to run the study is crucial from a feasibility and a costing/grant application point of view. If the research nurse has several studies, all requiring regular visits, then it may be impossible to add another study to his/her workload. The workload of a research nurse and forward planning of the research team portfolio can be notoriously difficult; studies may be delayed and suddenly several studies can become grant funded or their commercial contracts can become signed so that all want to be started within the same time period. From the grant application point of view, the research nurse should be involved in calculating the nurse resource required for the study. The cost of nurse time is always the most expensive category, but pressure to minimise this must be resisted to ensure recruitment targets and study milestones can be met. The research nurse must check his/her time to perform all the visits, recruit participants, deal with the data queries and paperwork, and communicate this with the investigator to ensure that the costings are accurate when the grant is submitted.

Feasibility is also influenced by many other factors, which I will continue to discuss these in next month's column. ■