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.

The research nurse must be an advocate for trial participants

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Over the last few months, I have looked at both the rules and regulations of clinical research and informed consent, so this month I thought I would discuss the importance of the research nurse acting as an advocate for people with diabetes throughout the trial. The International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use guidelines (ICH Good Clinical Practice, 2002) states that:

> *"The rights, safety and well-being of the trial subjects are the most important considerations and should prevail over the interests of science and society."*

Therefore, acting as an advocate for the people with diabetes involved in trials should be a major part of the day-to-day work carried out by a research nurse.

Participant advocate

So what does being the "participant advocate" actually mean? The Nursing and Midwifery Council Code of Conduct (NMC, 2008) states that:

> *"The people in your care must be able to trust you with their health and well-being...you must make the care of people your first concern, treating them as individuals and respecting their dignity".*

This applies to all people involved in research studies. There are several ways the research nurse can act as a participant advocate within the clinical trials process. When protocols and grant applications are being written, the research nurse can advise on what is fair and feasible to ask the person to do throughout the trial. For example, one study sponsor wanted to do intensive blood glucose profiling, which involved the person checking their blood glucose every couple of hours throughout the day and this included checking blood glucose at 2-hour intervals during the night. The sponsor also stated that this had to be carried out during the working week, and not at weekends. The experienced research nurse involved in the study suggested that this was a rather unreasonable request and that it was likely to prevent people participating in this study. By working with the sponsor, the research nurse suggested that continuous blood glucose monitoring could be used for this study, which was much more acceptable to the participants and ensured that the sponsor received complete data for the blood glucose profiling.

This example demonstrates that research nurses should not be afraid to challenge what they consider to be unrealistic expectations. Participants who enrol in studies generally will try their best to do everything that is asked of them but sometimes protocols can be very intensive and this can cause problems for both the people involved and the trial itself.

Informed consent

Acting as a participant advocate during the informed consent process is also very important. If the research nurse feels that the person is not truly informed or has not understood any aspect of the study, then he/she is professionally accountable for the process and should intervene. The nurse should ensure that all participants should either fully understand what they are signing up for, or stop the process. It is well known that often trial participants want to "please" the doctor or research nurse but, as I have discussed in previous columns, it is imperative that they truly understand exactly what is involved.

Clinical phase of a study

Throughout the clinical phase of a study, the research nurse should again take on a participant advocate role. This is best understood using examples.

Example 1: Participant experiencing adverse events

A participant is experiencing significant adverse events (side-effects) whilst on a trial of a new drug. In an ideal world, the participant should be taken off the clinical trial drug, left for a "washout period" and then re-challenged with the drug and this is usually what the sponsor would want. However, the research nurse, who knows the individual, is usually the best placed study team member to advise whether a re-challenge should be conducted or not. Participants often minimise any adverse events to the study doctor but will confide in the nurse about any difficulties they may be experiencing. Often they can feel like they have let the trial down by stopping taking a drug because of adverse events and the research nurse should work with the individual to ensure that they do not feel that it is their fault. Most studies today still follow-up participants who are no longer taking study drugs (for whatever reason), so it is easier for the research nurse to maintain her relationship with the participant as study visits continue as normal. Often there can be pressure from sponsors to keep participants on the study drug and the research nurse needs to be confident in their ability to defend their decisions and maintain the trusting relationship they have with the participants.

Example 2: Participant experiences a significant life event

This situation arises when a person with diabetes taking part in a study suddenly experiences a life event, such as a close bereavement or becoming a carer for a family member. In my years as a research nurse, most of the participants who have experienced an event such as this have not withdrawn from the study they are participating in but have gone on to complete all the study visits. However, at times such as this, the research nurse needs to be aware of the change in domestic circumstances and should assess with the person whether continuing in the study is in their best interests. Often, the routine of continuing the study visits seems to give the person a daily purpose or give them some respite from caring for a family member. However, it is important that there is an honest discussion between the nurse and the person, and they should be given the option to withdraw from the study.

Acting as a participant advocate is a rewarding part of a research nurse's role as it allows the nurses to develop relationships with the people involved in the study.

Example 3: A participant moves away from the area

A participant on a weight-loss study (who had lost lots of weight) went on holiday to the USA and fell in love with an American man. Within a few months, she married him and moved to the Bahamas. The sponsor company for the long-term cardiovascular outcomes study that she was participating in were not happy as she would be effectively "lost to follow-up" (in cardiovascular studies, lost to follow up means that the participant counts as dead and this impacts on the statistical analysis). The research nurse informed the sponsor company that the participant had moved and negotiated with the participant that she would email her at the regular study visits to check for adverse events and arranged to do her annual visit when the participant returned to Scotland each year to visit her mother. The study team in Scotland thought this was an excellent compromise and the sponsor company eventually accepted it as a solution. This example shows how the research nurse's negotiation skills managed to keep the participant in the study, albeit to a limited extent, and that her data would be valuable to the long-term outcomes of the study. Often sponsors are so keen to see their study succeed that they appear to forget that completing the study may not be every participant's top priority.

In conclusion, the role of the participant advocate is a really important part of every research nurse's post. It is often difficult to manage as the sponsor's demands of recruiting and retaining people in studies can be high, but this must be balanced by the needs of each individual participant. However, it is also one of the most rewarding aspects of the research nurse role as it allows relationship building and the feeling that one is making a difference. ■

International Conference on Harmonisation of technical requirements for registration of pharmaceuticals for human use guidelines (2002) *Guideline for good clinical practice*. ICH GCP. Available at: http://www.ichgcp.net (accessed 02.10.13)

Nursing and Midwifery Council (2008) *The code: Standards of conduct, performance and ethics for nurses and midwives*. NMC, London. Available at: http://www.nmc-uk.org/Publications/Standards/ (accessed 02.10.13)