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.

How should we conduct our research in line with medical research regulations?

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Rules, regulations, local policies and guidelines are all part of everyday life for all nurses but research nurses also have to be aware of and follow the myriad of medical research regulations. This month, I would like to discuss how to conduct your research ensuring that you are compliant with all the relevant legislation.

The Nuremberg trials at the end of World War II exposed the horrors of clinical research on uninformed human subjects for the first time and led to the World Medical Association (WMA) publishing the *Declaration of Helsinki* in 1964, which defined the ethical principles for medical research involving human subjects. This declaration has been amended eight times since then, with the most recent amendment in 2008, but its mission statement remains the same, i.e. "the well being of the individual research subject must take precedence over all other interests." The Declaration of Helsinki was then expanded to form the *International Conference on Harmonisation of Good Clinical Practice Guidelines* (ICH GCP). There are 13 principles of GCP and it is defined as "a set of internationally recognised ethical and scientific quality requirements which must be observed for designing, conducting, recording and reporting clinical trials that involve the participation of human subjects." Basically, GCP protects both the individual safety of subjects in a research project and the integrity and robustness of the data collected throughout the study. Conducting your study to GCP standards is seen as the "gold standard" for clinical research and most of the major scientific journals, such as the *Lancet* or *BMJ*, will no longer publish articles on studies that have not been conducted to GCP standards. All healthcare professionals involved with collecting any research data for a study (i.e. named on the "delegation of responsibilities" log) should have a current GCP certificate. Many NHS trusts and universities run GCP courses (usually a full-day initial course, followed by half-day updates) or there are online courses, such as that run by the National Institute for Health Research (NIHR). There has been debate as to how often GCP knowledge should be updated but it is generally accepted that, owing to the frequent changes in research legislation, those involved in clinical research should attend a refresher course every 2 years.

In 2001, the EU adopted the *EU Clinical Trials directive (2001/20/EC)* as a framework for good management in trials of medicines for human use and this became law in the UK in 2004 as the *UK Medicines for Human Use (Clinical Trials) Regulation*. This law is based on the 13 principles of GCP and can mean that serious breaches can result in imprisonment. Although the regulation relates specifically to medicines, researchers must be aware that any product given to a participant as part of a clinical trial, even if it is, for example, cranberry juice to ascertain if it can reduce recurrence of urinary tract infections, automatically becomes a clinical trial investigational medicinal product (CTIMP) for the course of the study and falls under the terms of the regulation. This law has again been reviewed and slightly amended in 2006 and 2008, with the latest amendment published in 2012. The main changes in 2012 concerned drug labelling and new pharmacovigilance reporting.

So, how do you conduct your research study without falling foul of any of the regulations? The simplest way is to become accustomed to running all your studies to GCP standards, whether they involve CTIMPs or not. This will mean more preparation before you start recruiting participants to a study but this time will have been well spent if your study is inspected by the Medicines and Healthcare Products Regulatory Agency (MHRA) or you are submitting any of your results for publication. Your study file must include records of training for all the study team in relevant procedures (including GCP), a delegation of responsibilities log and a risk assessment of all study procedures, as well as the study protocol and regulatory approval documents. Full details of all the essential documents that should be present in your study file are detailed on the ICH GCP website (www.ichgcp.net).

Every study procedure, from recruitment technique to recording blood pressure, should have a standard operating procedure (SOP). Some NHS Trusts now have these documents available but you may have to create your own for study-specific procedures, e.g. administering a quality of life questionnaire. Obviously, you do not have to create a whole set of new SOPs for every study as once you have a collection you can just choose the SOPs you need for a particular study. However, please be aware that you should be reviewing all your SOPs at least every 2 years to remain GCP-compliant. Superseded versions of SOPs must be archived. Copies of clinical SOPs are free to download from the Scottish Diabetes Research Network website (www.sdrn.org.uk) and adapt according to local practice but you should also check with your local research and development department as they may have similar documents.

The document, i.e. case report form (CRF), that all data are recorded in should be standardised to eliminate any anomalies. Again, many trusts now have both paper and electronic template CRFs which can simply be adapted for each study or you can create your own for current and future use.

With all study documentation standardised, and copies filed in the study master file, you will now be in a position to proceed with recruiting participants for your trial. Once the clinical phase of the trial is completed, data queries are resolved and the results are published, you should make arrangements to archive all the study documentation. Much of the documentation will need to be retained for many years (currently you must keep all documents from trials of a particular drug for 2 years after the last marketing application anywhere in the world) so there must be a plan in place before the start of the trial as to where the documentation will be stored post-trial. There are several companies that specialise in document storage so it is worthwhile discussing cost with them before the grant application stage so this cost can be incorporated.

As mentioned previously, versions of SOPs that have been subsequently superseded should also be archived (and the study file should show which version of an SOP was used for each study process). The reasoning behind archiving absolutely all the methods used in the study, as well as all the study documentation, is so that another researcher could retrospectively conduct the trial exactly as you did and check if the results are reproducible.

The principles above mostly relate to quantitative research and it is slightly more difficult to apply them all to qualitative research, particularly the reproducibility. However, the overriding aims of protecting participant safety and ensuring the quality of the data captured are just as valid for qualitative researchers.

So, in conclusion, as research nurses, we owe it to our patients who volunteer to take part in studies to conduct that research to the very highest standards at all times. ■

Shona Brearley highlights the importance, as research nurses, of complying with relevant medical legislation, and conducting research to the very highest standards at all times.