Research ethics and the ethics of research

Cicely Roche has worked in community pharmacy in Canada and Ireland since graduating from Trinity College Dublin in 1983. She holds an MSc in Community Pharmacy from Queen's University Belfast (2001) and an MSc in Healthcare Ethics and Law from RCSI (2007).

The operation of ethics committees in Ireland, regularly referred to in the literature as Research Ethics Boards (REBs), “are under the supervision of the Minister for Health, who may either recognise committees appointed by institutions or appoint her own committees with either national responsibility or responsibility for particular classes of clinical trials. Where the Minister recognises an ethics committee, she must indicate to them their terms of reference”. (Mills). Research for particular classes of clinical trials. Where the Minister recognises an ethics committee, she must indicate to them their terms of reference”. (Mills). Research for particular classes of clinical trials. Where the Minister recognises an ethics committee, she must indicate to them their terms of reference”. (Mills). Research for particular classes of clinical trials. Where the Minister recognises an ethics committee, she must indicate to them their terms of reference”. (Mills).

Research ethics boards may therefore be variable in their ‘modus operandi’. However, they must be dependent on an assurance that such atrocities could never recur. The 10-point Belmont report (1979) reaffirmed the requirement for consent, and added specific additional ethical principles which focussed on assurances that benefits and harm are balanced and that there is an equitable distribution between the burdens and benefits of research. Given the treatment of the residents of Tuskegee (amongst others), there is nothing I would think or write that would be intended to diminish attention to such injustice, or the desire to prevent a re-occurrence of same.

Notwithstanding the above, I do think that new approaches to practice-based research may be required. ‘Much health research is heavily dependent on access to information from medical records’ (Willison et al 2008). As privacy law and the protection of personal data have become more heavily regulated, access to medical records for research purposes has also become more tightly controlled. The debate has become somewhat focused on whether there is a risk that even anonymised data might be potentially identifiable. Debate suggests that the use of outside researchers or research assistants to gather data, rather than engaging the primary healthcare professionals themselves, increases the likelihood of such breach of privacy. Removal of unnecessarily specific identifiers such as date of birth, when ‘year of birth’ may be perfectly adequate and/or the utilisation of dispensing software to encode identifiers in such a manner that only the practitioner caring for the patient could subsequently re-identify the patient, are further approaches that could reduce those risks. Pharmacoeconomics research is currently facilitated by the provision of anonymised data from the PCRS – the weakness in that system being that the database, which excludes non-reimbursed medicines, is incomplete. It would appear that there is an undeveloped role that practitioners could legitimately play to be completely data available for research and collation purposes, the skill-set required for which is not unrelated to data review for quality improvements.

There should be no intention of diminishing respect for autonomy, or the rights to privacy or confidentiality, but rather to seek more appropriate means by which to maximise opportunities to promote the ‘greater good’ while adhering to the core principle of ‘do no harm’.

Going back to the patient who asked for advice as to whether I thought her involvement in this double-blind, placebo-controlled trial was in her best interest. I could not pretend that to be the case. I have to accept that encouraging a specific patient to involve herself in a double-blind, placebo-controlled trial is tantamount to telling her that a placebo is an acceptable element in her care. This type of scenario represents the classic conflict between patient-focussed care and a strategic approach to population health – a discussion topic particularly neglected in continuing education/professional development for community pharmacy practice.

Notwithstanding the detail of the above scenario, and the presumption that the GP represents the classic conflict between patient-focussed care and a strategic approach to population health – a discussion topic particularly neglected in continuing education/professional development for community pharmacy practice.


References –
• Willison, D.J. (2007) Data Protection and the Promotion of Health Research: If the Laws are not the Problem, Then what is? Healthcare Policy. 2(3): 39–43