

## Commentary on Armitage G (2005) Drug errors, qualitative research and some reflections on ethics. *Journal of Clinical Nursing* 14, 869–875

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There are many professionals involved in the process of medication including physicians, pharmacists and nurses. They each have their own roles in prescribing, dispensing and administering medication. Tasks related to medication are amongst the most frequent practices in health care organizations, and the consequences of medication error are well known. Thus, research on medication error is increasing.

The study of methodological and ethical issues related to qualitative methods is not a novelty in the literature (Mays & Pope 1995, Mangione-Smith *et al.* 2002, Mulhall 2003). Even the article of Armitage (2005) on drug errors within the National Health System in the UK using observational method points out the ethical issues surrounding it.

We agree with the points made by Armitage (2005) in his paper. To know the prevalence of drug errors is the starting point to improve professional competencies. Any gaps found in knowledge should become new opportunities for learning. Drugs errors should not be used to ruin a climate of openness and trust, or to blemish nurses' reputation when an observation reveals failures in the procedure. As we said before we agree entirely with these points.

Where we differ with Armitage (2005) is in the overall judgement that he makes on observational research primarily, because of our evaluation of the validity of these studies. Our suggestion is to modify certain aspects, which are in need of improvement. We consider that ethical issues should not be considered in isolation as Armitage does, but should be seen within the whole context of the problem.

Evidence exists to show that subject behaviour and study outcomes are altered as a result of the subject's awareness of being under observation. This phenomenon is known as the Hawthorne Effect and was first identified and described in the 1930s (Mangione-Smith *et al.* 2002). This effect distorts completely the value of any alternative approach: What is the sense of an observational study where participant consent has been given if validity is not guaranteed? We think that a blind one-way observation has its own purpose and can be used

under specific circumstances where it is needed. It is legitimate to observe participants without their knowing that they are being observed to know reality as it is (Robson 2002).

However, our argument includes three other points. Firstly, research on drug errors has to pursue the benefit of patients. Research conducted with the sole aim of knowing what is happening in the area of medication errors and from which no practical improvements will be derived is lame research. However, more ethical considerations have to be made.

Secondly, the goal of the observation has to lead to identifying errors in the system rather than placing blame on persons. Therefore, anonymity of the participants has to be preserved. We would like to contend that the respect for the participants comes not only from gaining informed consent and promoting transparency in the method but also from assuring a secure setting in which to work and a solution of the participants acute problems. To review systems and improve them by implementing changes that prevent errors promotes safer practices (Reason 2000). In this regard, the responsibility of health care organizations is huge.

Lastly, we would like to mention that to hide the intention of the researcher from the participants does not mean that errors will not occur. On the contrary, the principle of beneficence requires that when an error that can cause harm to a patient is observed, the observer has the ethical obligation to stop it. 'First do not harm', says the Hippocratic oath. Observers should be alerted in advanced of their potential pitfalls in their methodology such as possible danger to patients.

Although we defend the necessity of reviewing systems rather than persons, we cannot neglect professional accountability. The 'sense of perfection or error free practice' described by Armitage (2005) would not occur if regular assessment of nurses and other health professionals were present. An assessment in the real world is needed when looking at professional performance. This professional performance is shaped by different factors: individual, task, team, environment, equipment and tools, both organizational and cultural (Baker *et al.* 2003). Again, the responsibility of organizations appears huge in assuring the competencies of their professionals to promote safe practices.

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As Armitage (2005) states, there are several methods to determine the presence and the impact of medication error. However, no single method is sufficient in itself, and different approaches are needed to understand in detail the reality of drug errors. Precisely because we prefer multiple methods, we propose that anonymous reporting, questionnaires and interviews be combined with observational methods that review systems rather than blame persons.

Finally and despite the different opinions and approaches, we would like to highlight the importance of the institutions' Ethical Committees. The Committee's role in the analysis and approval of research studies is crucial. There is no doubt that an Ethical Committee in health care organizations is a guarantee for all research studies and protects the rights of patients, participants and researchers.

## RESPONSE

Díaz-Navarriaz and Seguí-Gomez (2006) are well informed on the subject of drug errors and unsurprisingly their commentary on my original paper is considered and constructive.

Two fundamental points are raised which, for me, are very instructive and promote the accountability around error, which they rightly stress as important. Firstly, a respect for research participants does not arise simply from gaining informed consent and making sure that they are clear about the method being employed; it also emanates from attempting to resolve their problems – which in the domain of error research includes their propensity to err – often related to system deficiencies. Secondly, regular assessment of health professionals, even if it might be through research, can reduce the myth of perfection in practice.

To add a little more to the debate, I have two small points and a conclusion, which raises a question and an answer. Firstly, as my colleagues have asserted, there is a plethora of literature on error research and the ethics of qualitative methods. However, there is little on the ethics of error research.

Secondly and methodologically, observational research studies are of course susceptible to the Hawthorne effect, but I suggest that there is a gradient of effect. It is greatest (or most important) in experimental or quasi-experimental research and perhaps less so in qualitative studies where the researcher may engage with the participants to gain more data, inevitably provoking a differing view of validity and the

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claims that might be made on the data. A different paradigm can mean a different notion of 'measurement'.

Finally, it is clear that the nature of the field gives rise to considerable sensitivities, about individual and organizational performance, and of course their respective accountabilities. The sensitivities are also sometimes exacerbated by coverage (e.g. media), which is not always cognizant of the context and the pressures under which health professionals often operate. Thankfully, this wider picture can be captured by carefully crafted qualitative methods. But, can accountability be increased by research methods such as disguised observation, even if it is legitimate? The answer is *yes* but with a caveat: that the methods employed, if qualitative, should capture the wider picture that is the context.

It seems my Spanish research colleagues and I share some common ground, we believe that rigorously implemented qualitative methods provide a great opportunity to engage with health professionals on the subject of error, whether they are based on interview, observation, or preferably multiple methods. Moreover, we have debated some of the ethical tensions in the field, which should be helpful to the future refinement of methodology and method alike.

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