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The New UK Research Governance: its Impact on Pharmacy Undergraduate Research Projects*

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Implementation of the Department of Health Research Governance Framework (RGF) in the United Kingdom has major implications for the conduct of pharmacy practice undergraduate research projects. This paper draws upon a survey of local ethics research committees (LRECs) in the greater Birmingham area to identify the issues that arise from the RGF in relation to non-clinical practice research in community pharmacy. Although there is some evidence of minor differences between LRECs, the overwhelming finding is that projects will be subject to the full force of the RGF. The implications are discussed in relation to specific issues relating to non-clinical research, the professional aspirations for a research capable workforce, and the expertise within pharmacy to meet the current accreditation requirements for undergraduate projects.

Keywords: Research Governance; Undergraduate Project; Community Pharmacy; School of Pharmacy

INTRODUCTION

The Research Governance Framework for Health and Social Care

United Kingdom Department of Health (DOH) guidance on research governance (Department of Health, 2001a) is currently having a dramatic impact on our approach to undergraduate research in our School of Pharmacy. This paper addresses the very topical issue of research ethics and undergraduate education since our experiences are being mirrored in all other schools of pharmacy in England and Wales.

For many years it was expected that research involving National Health Service (NHS) patients, staff or premises should receive the prior approval of a Local Research Ethics Committees (LREC) (Jesson, 1997). However, the non-NHS status of community pharmacy meant that many researchers undertook non-clinical pharmacy practice research, particularly at undergraduate level, without recourse to an NHS ethics committee. It is very clear from the abstracts of past Health Service Research and Pharmacy Practice Conferences (HSR/PP) and British Pharmaceutical Conferences (BPC) that undergraduate work has been an important element in advancing the evidence base of pharmacy practice. This contribution is now threatened by the DOH Research Governance framework (Department of Health, 2001b), which complements clinical and corporate governance guidance, and requires all health projects to be approved by an appropriate LREC (not just a university ethics committee).

As researchers we have always been aware of the importance and relevance of research ethics committee approval when carrying out research which involves the NHS and which is clinical or which involves medical practitioners or patients' medical records. Such work has normally been associated with major research projects such as commissioned research (Wilson *et al.*, 2002). The new framework has a number of objectives mainly concerned with quality and responsibility and it is intended to have wide applicability (Fig. 1). A stated priority is that it "pays particular attention to clarifying responsibilities and accountabilities".

The Royal Pharmaceutical Society of Great Britain (RPSGB) as a research funder has already

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Guidance

- To set new standards for health service research
- To define mechanisms to deliver standards
- To describe the monitoring and assessment arrangements
- To improve the quality of research and safeguard the public by:
  Enhancing ethical and scientific quality,
  Promoting good practice,
  Reducing adverse incidents and ensuring lessons are learned,
  Preventing poor performance and misconduct

It is for all those who:

- Participate in research
- Host research in their organisation
- Fund research proposals or infrastructure
- Manage research
- Undertake research
- It is for managers and staff, in all professional groups, no matter how senior or junior.

FIGURE 1 The DOH (4.RGF: p2) core objectives in launching the new guidance.

incorporated the guidance to ensure that all pharmacy practice research it funds has LREC approval. Although the process and procedures for such approval are not new, there are three new elements and these are described in numerous DOH research governance documents:

1. the issue of quality,
2. the inclusion of community pharmacy,
3. the inclusion of undergraduate research.

We begin by summarising the key issues in the new guidance, describe the results of a survey of guidance given by our local Research Ethics Committees and then discuss the implications as we see them for our own pharmacy research practice.

When do We need Ethical Approval from NHS Research Ethics Committees (REC)?

The new Research Governance Framework (RGF) (Department of Health, 2001b) reinforces all previous DOH advice on research. In this context, research is defined (section 1.7) as "the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods".The framework applies to all research carried out in or by the NHS in England and Wales, including joint projects undertaken with universities, pharmaceutical companies, charities and research councils (Fig. 2). Thus the remit of an NHS LREC is wide and the guidance to LRECs, "Governance Arrangements for NHS Research Ethics Committees" (Department of Health, 2001a), makes explicit reference to undergraduate student projects (section 10.4). This shows little compromise stating, "Research to be undertaken by students primarily for educational purposes (e.g. as a requirement for a University degree course) shall be considered according to the same ethical and operational standards as are applied to other research. In such cases the supervisor takes on the role and responsibilities of the sponsor. In reaching its decision, the REC will wish to consider the broader overall benefits gained by such research."

We return to discuss the ambiguity of the place of pharmacy in the NHS later. But it is difficult to envisage how we might undertake any meaningful pharmacy undergraduate HSR in the future without having LREC approval. The next section describes the academic pharmacy context of the undergraduate research project.

The Pharmacy Context: Education and Professional Accreditation

The pharmacy and education context is set by the RPSGB requirements for degree accreditation, revised 2002 (Royal Pharmaceutical Society of Great Britain, 2002). These must accord with a European Union (EU) directive (85/432/EEC) on pharmacy education which provides general

Ethical advice from the appropriate NHS REC is required for any research proposal involving:

- Patients and users of the NHS.
- Individuals identified as potential research participants because of their status as relatives or carers of patients and users of the NHS
- Access to data, organs, or other bodily material of past and present NHS patients
- Foetal material and IVF involving NHS patients
- The recently dead in NHS premises
- The use of, or potential access to, NHS premises or facilities
- NHS staff - recruited as research participants by virtue of their professional role

FIGURE 2 The Remit of an NHS REC (Governance arrangements for NHS Research Ethics Committees: 7).

requirements in relation to syllabus. This directive makes no reference to an undergraduate project but there is a 1994 recommendation from the EU Advisory Committee on Pharmaceutical Training that "each student should carry out a personally directed research project covering about three to six months under the supervision of the academic staff and present a paper or dissertation on the project". This recommendation has been encapsulated within the RPSGB accreditation specifications that make an undergraduate research project a specific requirement and that also provide a limited definition of the project in terms of student workload and activities (Fig. 3).

Although the project is obligatory, the RPSGB criteria that define graduate qualities and the pharmacy undergraduate degree make little reference to research and the only outcome criteria linking research with graduate capability is that graduates should be able to "apply appropriate research approaches and methods to manage scientific and practice problems". This level of capability is, however, in accord with the aim articulated within the report of the Mays Taskforce on pharmacy practice research (Royal Pharmaceutical Society of Great Britain, 1997) that 100% of pharmacists should be "research users".

Whilst fulfilling the RPSGB undergraduate curriculum requirements, our educational aim as a school of pharmacy is that the compulsory research project should be a true learning experience for the student. For our own personal and professional development we want as staff to work with our undergraduates to produce good quality research, which is interesting, meaningful and from which we can all benefit. In our particular cases, we also want to add to the evidence base of pharmacy practice. This we achieve through dissemination of the research findings, an activity that has been successful for several years now. This includes the discussion of research issues at

"The degree course includes a significant research project of three to six months duration, but not necessarily with all curriculum time during this period devoted to this activity alone. The student must undertake the project alone or as his/her individual contribution to a team endeavour. The project must address a research question or problem, must involve a critique of research methodology employed, must include an analysis of results generated directly by the student or indirectly by others as primary researchers".

Footnote: "Thus all of laboratory, clinical, survey-based, behavioural and literature based projects are permissible".

FIGURE 3 RPSGB accreditation criteria 5—the requirement for an undergraduate research projects.

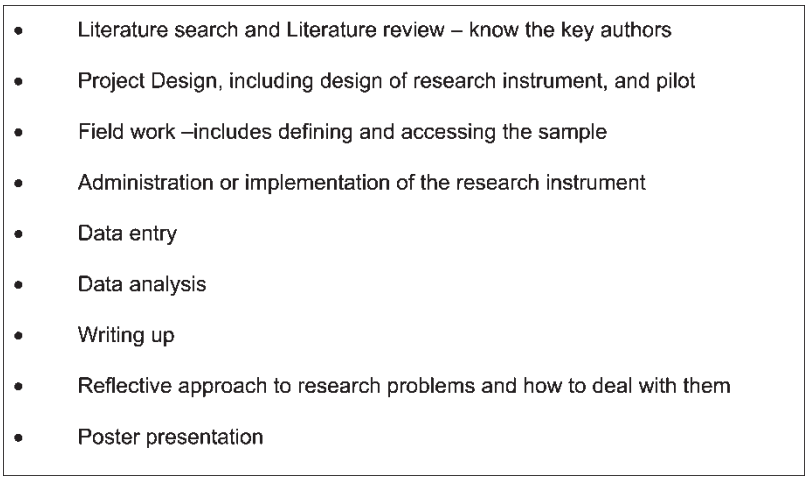

FIGURE 4 Core research process tasks in the undergraduate project.

conferences, not just within pharmacy at the HSR/PP and BPC, but also outside the profession at the British Sociological Association (BSA Medsoc), and UK Public Health Forum (UKPHA). As a consequence students benefit from the promotion of their work and gain the advantage of publication in their name.

In our school it is an educational aim that students must address within their project each of the core research process components shown in Fig. 4. It is, therefore, inappropriate for the research supervisors to design the project and the research instruments since this would mean using the students as research assistants with a reduction in their learning. Our own projects are firmly based in the social sciences methodology and techniques, not in clinical interventions. Up until now we did not believe it to be appropriate to submit undergraduate research projects to LRECs since they are learning vehicles, they are pharmacy or service based and not clinical interventions, they do not involve NHS staff but are focussed upon either process or upon the views and experiences of general members of the public.

The main difference between our core process tasks and the RPSGB guidance is that the latter does not refer to performance of research, fieldwork or the design and development of the research method. Whilst the RPSGB focus upon critical evaluation of the method and interpretation of results will develop research awareness, it has always been our educational aim to support attainment of the aim in the Mays Report (Royal Pharmaceutical Society of Great Britain, 1997) that 10% of pharmacists become "research practitioners" and 1% "research leaders".

In our school, projects take place in the second term (10 weeks) of the final undergraduate year with selection of titles by the students during the first term. The new research framework, therefore, has major implications since all research instruments must be submitted to the LREC at the time of approval. It appeared that to meet our educational objectives and the needs of the approval process there would need to be a major rescheduling of the process.

Before making any significant changes in our approach we sought advice from the relevant LRECs, using contact addresses listed on the DOH website for the region. The aim of the survey was to seek clarification and make some negotiation on the best way forward to manage undergraduate community pharmacy projects.

METHODS

Letters describing our research programme and concerns about timescales were posted to the nine West Midlands LRECs, in preference to e-mail or telephone, in mid-October 2002. The letter made clear that the nature of the research was not clinical and would not involve access to confidential patient records or affect therapy. We described four broad themes of work based upon our own recent research programme and chosen to reflect HSR rather than clinical research:

- primary care pharmacist (functions, responsibilities, educational needs)
- electronic transfer of patient data (policy, patient and prescriber views)
- services to drug misusers in the community (management of services, nature, needs analysis)
- health centre pharmacies (service development, patient and health professional views).

Replies were received from five of the nine by January 2003. A follow up letter was posted to the four non-responders in mid February 2003. A further two replies were received by March, leaving two outstanding.

Following analysis of the replies, a further communication was made by letter to the Primary Care Trust (PCT) Research Administrator, in March. The six months that passed in attempting to clarify our position says a lot about the administrative capability of the LRECs, and an apparent lack of urgency demonstrated by respondents.

RESULTS

The written responses varied in the quality and amount of information supplied to us by the eight LRECs. Only one explained that changes were still taking place and that the committees hope to have their procedures put into practice by October 2003. This does help us to understand the slow responses as a consequence of an "organisational flux" context. We report in particular on: general advice given, issues of research process management, particularly the confirmation of LREC approval, the time scales involved, methods and sampling.

General Advice

Whilst one respondent just enclosed their standard letter and documentation for the LREC and Multicentre Research Ethics Committees checklists without comment to our query(s), most of the others made reference to the DOH website, the Governance Arrangements for NHS Research Ethics Committees documentation quoting the relevant paragraphs three and ten and to a named contact at the Central Office for Research Ethics Committees for further queries. All respondents confirmed that we must have all research reviewed by a LREC. Some were more sympathetic to our particular problems than others.

> "I fully appreciate the problems that you allude to, they are exactly the same problems faced by medical students"(A-1).

> "There is no shortcut, if students are to gain an understanding or insight into conducting research an application to the REC is integral to the process " (B-2)

> "REC procedures are in place to safeguard patients and staff and apply equally to student's projects, although unfortunately their applications are often of a low standard" (B-3)

Time Scales

Most LRECs met monthly, one advised of bi-monthly meetings. In general respondents stressed that the responsibility to meet the imposed timetable rested with the project supervisor. This reinforced the message that student projects will be treated as any other piece of work.

> "The way to get a quick answer is to get the documentation correct first time round", (C-1)

> "The safest way forward is for your students to submit their projects to us for the first six months, so that we can judge whether it is in fact necessary for student research projects to come to the Committee" (A-2).

> "Increase the lead in time provided by the University" (B-4)

> "I note your concerns regarding short timescales for project modules, at present the REC holds bi-monthly meetings—if urgent need for approval may give provisional approval" (D-1)

> "I understand the timescales but suggest careful planning " (E-1)

Approaches to Methodology and Sampling

Our letter made reference to the use of surveys to determine the views of patients and health professionals. The responses were inconsistent. One LREC was clearly uncertain as to the nature of pharmacy practice research but expressed the view that any questionnaire would need to be reviewed.

> "There may be some difference in the pharmacy undergraduate research project (compared with medicine) if they do not utilise patients or do not use patient questionnaires " (A-3)

> "If there is any suggestion that pharmacy undergraduates will be using questionnaires, either to ask NHS staff or patients, they will certainly need to come to committee" (A-4)

Another LREC distinguished between "patients" and "members of the general public" on the basis of the purpose of the study while a third stated more broadly that patient satisfaction surveys would not require approval.

> "Questionnaires should always be submitted if they address anyone in their status as patient, relative or carer. This includes, for example, "members of the public" approached through general practitioners, but not those approached in a shopping centre, nor questionnaires to other students, for both of which school/department review procedures should be developed" (E-2)

> "In general patient satisfaction survey would not require ethical approval unless they were asking sensitive or personal questions of patients" (B-5)

One response also raised the issue of the distinction between audit and research.

> "If the committee judges them to be audit rather than research they will reply accordingly" (E-3)

New Structures—Pharmacy and the Primary Care Trust (PCT)

Primary Care Trusts are local health organisations responsible for managing local health services, PCTs work with local authorities and other agencies that provide health and social care locally to make sure the community's needs are being met.

Probably the most useful and important new information about pharmacy came from one LREC who noted that under the RGF (2001) (Department of Health, 2001b) responsibility for research is shared

by the Research and Development department in Trusts. The LREC had itself received communications from the Research and Development manager of one of the four Birmingham Primary Care Trusts, which has overall management responsibility for research over Birmingham. As part of the clinical governance arrangements, research must receive approval from this source following approval by an LREC. The advice from the research manager with respect to the position of community pharmacy was explicit:

> "Community pharmacists come under the remit of the PCT therefore all ongoing research within the community setting needs to be registered with me—the PCT has a duty of care to its patients and for that reason we need to be aware of the projects"

DISCUSSION

In its degree accreditation specification, the UK statutory regulator for pharmacy makes a specific requirement for a final year research project (Royal Pharmaceutical Society of Great Britain, 2002). In our own School of Pharmacy there has been a steady increase in the popularity of practice related projects to the point that these now account for around one third of all projects. Therefore the introduction of the new NHS RGF (Department of Health, 2001b) is of very direct relevance to undergraduate pharmacy education. As has been explained, our interest and the subject of this paper is the area of non-clinical pharmacy practice research. Our study has shown that there is national guidance, but maybe some variation at local level in interpretation over subjects and methods. Much of the variation of opinion appeared to be due to a lack of familiarity with community based pharmacy practice research and the nature of community pharmacy.

The Ambiguity of Pharmacy, Public and Market Research

We would argue that there are still some fundamental problems for implementing research governance within the pharmacy undergraduate research project. The three most important concepts for us are the nature of community pharmacy, the role of the general public in relation to community pharmacy and the scope of research within community pharmacy.

Firstly, in the case of pharmacy, community pharmacies (the premises) are private sector organisations delivering a service to the NHS under contract. They operate in a competitive retail environment and pharmacists are private sector not NHS employees. Much of the research on activities and services within the sector does not involve confidential information or clinical matters. As such it appears to us that it is arguable whether such research is covered by the terms of the NHS RGF. In this respect the apparent role of the PCT research and development manager in approving research in the community sector is of interest. Whilst there is a clear clinical governance issue in relation to research carried out within the NHS funded PCTs, it is less clear that an NHS funded management has a similar responsibility within private contracted organisations such as community pharmacies.

Secondly, there is the concept of patients as distinct from the general public. It is clear that members of the public as patients within an NHS setting are covered by the research framework, but this is less clear when we are conducting research with members of the public in their capacity as pharmacy customers or users of pharmacy services. The varied guidance given by our LREC replies recognise this inconclusiveness.

The above arguments come together when considering the nature of research carried out in community pharmacy. The companies that operate community pharmacies must undertake market research to maintain their position within an increasingly commercial retail sector. There is clearly overlap between this and pharmacy practice research with a major difference that external practice research, as undertaken in student projects, is intended to be made public. From our previous communications with and involvement in private sector research, we believe that it is highly unlikely that market research undertaken by the pharmacy multiples will be submitted to LRECs. Similarly, it seems probably that the major pharmaceutical companies will presumably also continue to do their own market research within general practice under without reference to LREC approval. We would argue that there should be consistency in the application of the research ethics framework based upon the nature of the research.

Implications within Pharmacy Practice: Quality and Capacity?

Notwithstanding the conceptual ambiguity, the new research framework has significant implications for undergraduate research within schools of pharmacy. It is clear from the responses that we received that there is no compromise in respect of undergraduate project work. Research to be undertaken by students primarily for education purposes, even though often of limited scope, will be considered with the same ethical rigour and operational standards as are applied to other research. This poses the schools of pharmacy with a double challenge: ensuring the quality of the research and the capacity to supervise it.

Within each student cohort there are variable levels of capability and skills. Educationally, a primary aim of the project is to develop and improve research capability during the course of the module. Yet the RFG minimum requirements of research governance systems demands absolute standards at the outset and place the responsibility upon the research sponsor (Department of Health, 2001b):

- "The research proposal must be worthwhile, of high scientific quality and represent good value for money" (RGF 3.8.6)
- "The arrangements and resources proposed will allow the collection of high quality, accurate data" (RGF 3.8.6)
- "Research which duplicates other work unnecessarily or which is not of sufficient quality to contribute something useful to existing knowledge is itself unethical" (RGF 2.3.1. 12)

One LREC recognised our concern about standards. Final year students have to submit their own research design to a professional audience for approval prior to implementation, yet have not had time to develop such skills. Furthermore, the research framework requires that as active member of the research team (a researcher); students must have demonstrable research capability:

> "Each member of the research team is qualified by education, training and experience to discharge his/ her role in the study" (RGF 3.6.3:25)

The ability to improve pharmacist capability is therefore dependent upon the capabilities of the academic supervising staff, and their ability to ensure that the student and the research meet LREC standards. Implementation of the RGF places enormous demands upon staff. In the case of student projects, the internal staff member, as the project supervisor, assumes the obligations as sponsor of the research and therefore the overall responsibility for ensuring compliance with the framework (Department of Health, 2001a). In most cases, the supervisor will also be the principal investigator and must, therefore, assume a range of specific responsibilities detailed in section 3.6 of the framework (Department of Health, 2001b):

> "The principal investigator must have the necessary expertise and experience to conduct the proposed research successfully"

> "Principal investigators must have suitable experience and expertise in the design and conduct of research so that they are able either to undertake the design, conduct, analysis and reporting of the study to the standards set out in this framework or to lead and manage others"

In our view this raises another dilemma. We appreciate that this critique will not be well received by many, but pharmacy practice research is a discipline which is relatively new (Nuffield Foundation, 1986) and, from our joint personal experience of 14 years in the practice research community, has had to struggle to meet acceptance within the pharmacy academic profession. The RPSGB Workforce survey showed that only 5% of the pharmacy profession has a Ph.D., 15% a Diploma. 43% of those who work in academia have a Ph.D. (Hassell and Shann, 2003). Application of the RGF to the final year project changes the nature of the exercise from a learning process to a full scale piece of research. It is not clear that there is the research capability within the schools of pharmacy, let alone the profession, to support this.

Moreover, the capacity of LRECs themselves to cope with all student projects in the area is questionable. In Birmingham we have three universities, which produce an annual output of pharmacists, doctors, nurses and other professions allied to medicine. Then there is the capability of the members of LRECs themselves, many still based in secondary care locations, consisting of clinical professionals, who in the past had difficulty relating to primary care, health services and social science based research studies. This observation is based on our own experience and the frequent outpouring of communications within the medical press about the shortcomings of the quality of decisions (Nicholl, 2000; Lyon, 2002). Assessing hundreds of undergraduate projects each year is not an efficient or cost effective use of LREC resources. None of the student projects will involve patient harm, clinical intervention or fraud.

The Way Forward

From a university perspective there are practical changes that we have to make, to comply with the research framework. We probably have until March 2004 when all active NHS care organisations should comply with the RGF, to reorganise the project module. First there is the issue of time tabling and time scales, which the LREC responses recognised. In our own school, the final year project takes place over ten weeks in second term of the fourth year. If we must have prior approval for anything other than very simple attitudinal student based sampling, then that cannot continue. One possibility is to split the project over two terms and to teach research proposal and research instrument design early in the first term, and then carry out the project in half of the second term. This would have major implications for other subject timetabling for the whole year cohort but most importantly, it raises the question as to how to proceed if a students submit a proposal in the first term and the LREC asks for a redesign or issues a rejection. Furthermore, what does that often brutally worded rejection do to student confidence?

There are, however, wider implications. From an educational perspective, we think that the RPSGB needs to reconsider the requirement that all students complete an "extended" undergraduate research project. This is articulated in criteria five of the accreditation document (Royal Pharmaceutical Society of Great Britain, 2002) and it is stated to be a pre-requisite dictated by EU requirements. However, the origin of this requirement is not the primary EU directive on Pharmacy Education, directive 85/432/EEC, but instead it is one of a number of recommendations made in 1994 by an EU Advisory Committee on Pharmaceutical Training, itself set up under directive 85/434/EEC. These recommendations are now almost a decade old and were made in a different educational and funding climate and prior to the DOH RGF and the many issues that lead to it such as the debate on professional responsibility in the wake of the Bristol Heart Review (Bristol Royal Infirmary Inquiry, 2001).

In our view, the key question is as to the purpose of the project. Criteria five of the RPSGB accreditation document specifies that the project must "address a research question or a problem, must involve a critique of the research methodology employed, and must include an analysis of results generated directly by the student or indirectly by others as primary researchers". There is, therefore, apparently no requirement for the student to plan the research, to design the research methods or to undertake the research—field work in a pharmacy practice context. Furthermore, the only criterion on graduate competencies that addresses research, criteria 21, merely states that the graduate "can apply appropriate research approaches and methods to manage scientific and practice problems". In the context of the Mays report on pharmacy practice, this appears to equate to the lowest level, the "research user." This is appropriate as an objective for all students but as educationalists we have always regarded the project as a key element in the development of "research practitioners" and therefore of future "research leaders". There are many ways of developing research awareness but not, we would argue, of engendering research practitioners. In the increasingly restrictive research governance environment, there appears to us to be a need to review the intended purpose of the project and therefore the requirement that all students undertake a project.

Finally, we believe that this new tension between research governance and risk management of clinical research has reinforced the level of bureaucratic social control that an unaccountable body will have over schools of pharmacy and pharmacy practice research. We predict that it will destroy innovation and stifle creativity in pharmacy practice, as staff may choose projects that are mainly literature reviews and student sample based studies. Most important of all though is our belief that far from setting new standards for HSR, protecting participants in research, and improving the quality of research, the new framework will limit the student experience and make it more difficult to develop practitioners who will be the future research leaders.

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