The research governance agenda: A new experience

Julia Shaw, Ciara Hughes, Katie Lagan

Introduction

Within Northern Ireland, various bodies exist to promote, coordinate and support research and development regionally. A Framework (Department of Health, 2005) has been developed to deliver the research governance agenda by setting standards, describing monitoring and assessment arrangements, enhancing ethical and scientific quality and preventing poor performance and misconduct. This paper details the processes required to ensure that all legal requirements are met in order to successfully manufacture a novel drug-containing dressing and to conduct a randomised, controlled clinical trial to evaluate the effect of this dressing on healing in the ulcerated diabetic foot. Similarities may be drawn between the processes outlined in this article (such as applications for ethical approval) and those which may be in place in other UK regions.

In Northern Ireland, Health and Social Services are integrated and delivered jointly under the umbrella of Health and Personal Social Services. The Department of Health, Social Services and Public Safety is involved in the delivery of health care to the public (http://www.dhsspsni.gov.uk [accessed 27.10.2005]).

At present, four health boards are responsible for assessing the needs of the population in Northern Ireland and commissioning the services required to meet those needs. The 19 trusts within Northern Ireland are responsible for providing those services that are commissioned by the boards to the population.

Various bodies also exist as Health and Social Services Agencies. These bodies have a regional role and include the Central Services Agency, which supports the Research and Development Office (RDO).

Research and Development Office

The RDO was established to promote, coordinate and support research and development within Northern Ireland (http://www.bionorthernireland.com/pooled/profiles/BF_COMP/view.asp?Q=BF_COMP_9160 [accessed 27.10.2005]). It has a dual role of strategically providing direction for the Health and Personal Social Services and operationally supporting initiatives from education and training to direct commissioning.

Research Governance Framework

The *Research Governance Framework for Health and Social Care* outlines elements required to successfully deliver the research governance agenda of the RDO at a strategic level on a regional basis (Department of Health [DoH], 2005). The document is designed to be used by all professional groups at all levels. In brief, the document sets out a Framework for the governance of research by setting standards, defining mechanisms to deliver these standards, describing monitoring and assessment arrangements, enhancing ethical and scientific quality, promoting good practice, aiming to reduce adverse incidents, and preventing poor performance and misconduct.

Clinical Research Support Centre

A regional Clinical Research Support Centre (CRSC; http://www.crsc.n-i.nhs.uk [accessed 27.10.2005]) situated at the Royal Victoria Hospital, Belfast, was established in 2002 to help deliver the research governance agenda of the RDO, as described in the Framework

ARTICLE POINTS

1 In Northern Ireland, the Research and Development Office was established to promote, coordinate and deliver the research governance strategy on a regional basis.

2 A robust research governance process must involve insurance of project quality, completion of relevant documentation, granting of final approval and indemnification of all projects.

3 Since 1 May 2004, regulations have dictated that any dressings, drugs and devices to be used on humans must be manufactured to a high standard in licensed premises.

4 Non-commercial clinical research will be challenging in this new environment.

KEY WORDS

- **Research strategy**
- **Research Governance Framework**
- **Dressing trials**

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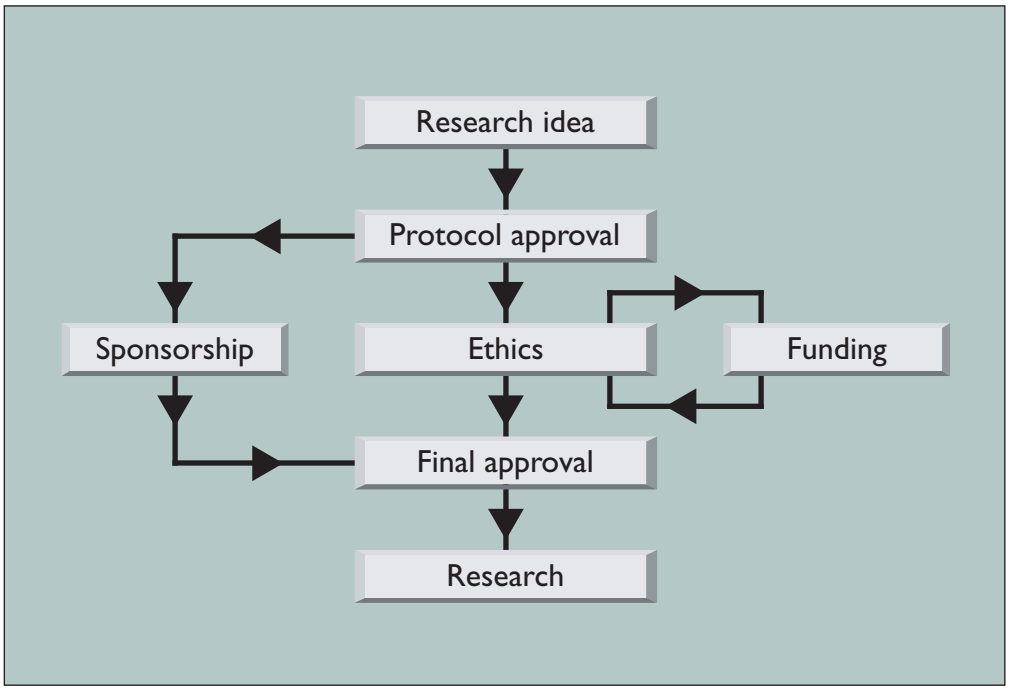

Figure 1. The basic flow for projects within the divisions of the Royal Victoria Hospital, Belfast.

document outlined above. The objectives of the CRSC, in brief, were to deliver the research governance agenda and promote the spread of a culture of high-quality research throughout the hospital and, ultimately, Northern Ireland as a whole.

Recognised Research Groups

The RDO has facilitated the development of eight Recognised Research Groups (RRGs), designed to enhance high-quality research. They also serve to promote a culture of enthusiasm for research among NHS0 staff. One of the eight RRGs, the Trauma and Rehabilitation RRG (http://www.rrg.unite.net [accessed 27.10.2005]), has developed several active themed sub-groups, one of which is the Wound Healing Research sub-group. This is a multidisciplinary group with nursing, general medicine, physiotherapy, podiatry, dentistry, pharmacy, bioengineering, imaging and academia represented. The sub-group is continuing to search for affordable and realistic ways to maintain tissue integrity, accelerate healing rates and improve outcomes, and therefore quality of life, for patients. (It was through the RDO and the Wound Healing Research themed sub-group that funding was secured to finance the project described here.)

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Legal considerations

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Medicines and Healthcare products Regulatory Agency

The Medicines and Healthcare products Regulatory Agency (MHRA) is the executive agency of the DoH and is

> ***'committed to safeguarding public health by ensuring that medicines, healthcare products and medical equipment meet appropriate standards of safety, quality, performance and effectiveness, and are used safely' (MHRA, 2005b).***

This body replaced the old Medical Devices Agency and Medicines Control Agency and has a major role in the implementation of the new Clinical Trials Directive (2001/20/EC; fully applicable from 1 May 2004; MHRA, 2005a). The main objective of the Clinical Trials Directive is to

> ***'simplify and harmonise the administrative provisions governing clinical trials by establishing a clear, transparent procedure and creating***

conditions conducive to the effective co-ordination of such clinical trials in the European Community by the authorities concerned' (MHRA, 2005a).

More generally, the Clinical Trials Directive aims to provide protection for individuals (including healthy volunteers) participating in clinical trials, without hindering the discovery or production of essential new medicines and devices.

The MHRA is also the competent authority for medical devices and the licensing authority for pharmaceuticals. It must be approached for a Clinical Trials Authorisation (CTA) for all clinical trials involving the use of licensed and unlicensed drugs, dressings and devices.

All clinical trials that began after 1 May 2004 require a CTA and will be entered into a database containing information on all interventional clinical trials of medicinal products in the European Community. Each trial will be issued with a EudraCT number, which is obtained from a secure site and allows the investigators to enter details of the trial onto the database (http://eudract.emea.eu.int [accessed 27.10.2005]). It is essential to have a CTA in order to obtain full ethical approval from the appropriate ethical committee.

Ethical approval

The process of gaining ethical approval for clinical research changed in April 2004. (It should be noted that ethical approval for the project described here was obtained using the previous system.)

The Central Office for Research Ethics Committees (COREC; http://www.corec.org.uk [accessed 27.10.2005]) was set up on behalf of the DoH in England. The remit of the committee (COREC; 2005) is as follows.

1 To coordinate the development of local and multicentre Research Ethics Committees on behalf of the NHS in England.
2 To guide the DoH on a review of the process if the need arises.

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ERRATUM

The role of pH modulation in wound bed preparation
Volume 8 Number 3, page 157, column 1, paragraph 2.

A sentence read:
It consists of a matrix of cross-linked carboxylated starch beads in a PEG/PPG (polyethylene glycol and polypropylene glycol) carrier.

It should have read:
It consists of a matrix of cross-linked carboxylated starch beads in a PEG (polyethylene glycol) carrier.

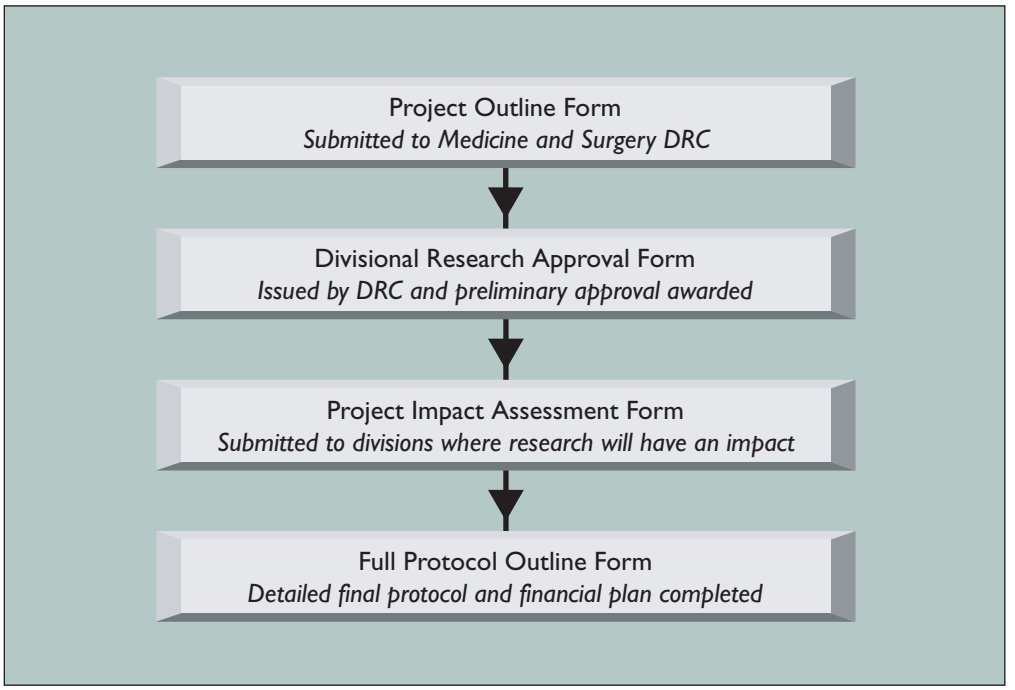

Figure 2. The flow of approval for the project described here (DRC = Divisional Research Committee).

3 To manage multice ntre research committees.
4 To develop and manage a national training programme for committee members and administrators.
5 To establish and manage regional Offices of Research Ethics Committees (ORECs) in Scotland, Wales and Ireland.
6 To advise the DoH on the implications associated with the implementation of the EU Directive on Good Clinical Practice in Medicinal Trials in the UK.

Within Northern Ireland, three OREC committees have been established. These groups meet at least monthly and guarantee that ethical approval will be given or denied within 60 days of application. Investigators may apply to have amendments made to their submissions, with a decision given within 35 days. Applicants may also be invited to be present when their application is being considered.

Local research governance

The majority of clinical research in Belfast and the surrounding area is conducted within the Royal Victoria Hospital, Queen's University Belfast and the University of Ulster, where there is a strong teaching and research culture among staff. The Royal Victoria Hospital is supported in this venture by the Royal Research Office, which ensures that all principal investigators comply with research governance procedures, that projects are of a high scientific quality, that trials are managed and that study participants are protected. Financial probity is paramount, and the Royal Research Office and Royal Victoria Hospital must be aware of, and control, all expenditure arising from every research project.

The research governance process within the Royal Victoria Hospital is based on a system of Divisional Research Committees (DRCs) that are overseen and facilitated by the Royal Research Office. These committees mirror the organisational structure of the Royal Victoria Hospital and each division has its own research committee. The initial role of the DRCs is to ensure that an individual project's strategy mirrors that of the division and to award preliminary approval. The DRC then peer reviews the project to ensure high scientific quality (if deemed appropriate), ensures that the relevant documentation is completed to satisfy the research governance process, grants final approval and ultimately indemnifies the study so that it can begin (the basic divisional flow for projects is shown in *Figure 1*).

Each DRC is chaired by a divisional research lead (a senior consultant), and

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committee members include a divisional manager and accountant and a member of each profession or speciality represented in that division. There is recognition that the DRCs must accommodate nursing and allied health professions research. Each committee has the right to delegate scientific peer review to sub-groups, where they exist, or to the RDO or another agency.

In order for a project to progress through the research governance process, investigators must decide where the project sits in the divisional structure and must identify which DRC the initial application must be made to. Investigators must then complete a suite of documentation in order to progress through the process (*Figure 2* illustrates this, using the project described here).

The Project Outline Form outlines the project and can be submitted to the DRC with or without ethical approval and with or without a firm commitment from a funding body. Preliminary approval is awarded with a Divisional Research Approval Form. At the second stage of the process, Project Impact Assessment Forms are completed and submitted to each DRC that the project will have an impact on. Important elements in this form are the question asked, the study design and the impact on the divisions. The final part of the divisional process is the completion of the Full Protocol Outline Form. This form is a summarised version of the study protocol, and detailed, accurate information is required on the use of finances and resources in the study.

The project

Aims

The main aims of the project were to manufacture a novel dressing for use in the management of diabetic foot ulceration, and to conduct a clinical trial to investigate the dressing's effect on the associated wounds.

Dressing manufacture

In the project, a drug-containing dressing was developed in the Pharmacy Department of Queen's University Belfast. Relevant tests were carried out to ensure that standards were met for stability, drug release and irradiation. Owing to the new regulations governing the manufacture of dressings and devices, the manufacture of the dressings had to be transferred to the only licensed premises within Northern Ireland (Victoria Pharmaceuticals, Belfast), at a considerable additional cost.

Clinical trial

A double-blind, prospective, randomised, controlled clinical trial to evaluate the effect of the novel drug-containing dressing on healing in diabetic foot ulcers has been designed. Ethical approval has been obtained and the in-house research governance procedure has been successfully completed. The application to the MHRA for the CTA has been successful, dressing manufacture is in the final stages, and the randomised clinical trial is set to begin.

Discussion

There is a commitment from the Government and trusts to enhance the contribution of research to health and social care. The Research Governance Framework should ensure that the research process is delivered in a unified and standardised fashion throughout the UK. All regions will be charged with implementing the same processes and procedures to ensure good practice.

Professionals are charged with supporting high-quality management plans with an evidence base and high-quality research. In order to achieve this, the partnership between science and services must be strengthened. A robust research management system is required if an organisation, and the investigators therein, are to safely deliver the research governance agenda. Undoubtedly, the safety of participants is paramount.

The research itself should be of the highest quality and standards must be upheld. In addition, financial transparency must be apparent with the use of public money and the influence of industry. Responsibilities of the various bodies and the investigator must be identified and discharged successfully.

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dressing has been exciting and challenging, but daunting. The process has provided an opportunity for the lead author to follow the development of a product through the process from conception to trial. The pharmacists involved in the project have provided invaluable help and advice in the MHRA application for a CTA and in the production of information required. The CRSC has provided advice and expertise on clinical trial design. In addition to these bodies, the Royal Research Office has been invaluable in coordinating the process and negotiating between divisions in the research governance process.

The lead author has had the opportunity to consider this process from both sides, as a DRC member and an investigator. First appearances suggest that the process is a very complex one. The investigator must be knowledgeable on the clinical, scientific and financial aspects of the study in question.

The authors believe that the development of a detailed research protocol and a general willingness to network with various bodies and individuals related to the study is essential in order to achieve a successful outcome. The research governance process is undoubtedly governed by the complexity of an individual study. It is worth noting that allied health professions research has the potential to impact on several divisions across a large trust. In addition, the process always seems to take longer than expected.

Conclusion

New research governance processes are daunting to those researchers with limited experience and genuine concerns have been raised that the whole process will discourage research because of cumbersome red tape (Jeffcoate, 2004; Al-Shahi, 2005). Within the NHS, the registration and administration process required with the MHRA may simply prove to be too expensive in the current financial climate.

In the authors' opinion, however, professionals involved in the management of the diabetic foot believe passionately in what they do and strive to improve patients' quality of life. If this is yet another challenge to be overcome then, undoubtedly, the process will be managed innovatively with the resilience and hard work which has been associated with this multidisciplinary group of professionals over the years. ■

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Clinical Research Support Centre	http://www.crsc.n-i.nhs.uk
Department of Health, Social Services and Public Safety	http://www.dhsspsni.gov.uk
European Clinical Trials Database	http://eudract.emea.eu.int
Trauma and Rehabilitation Recognised Research Group	http://www.rrg.unite.net