
Editorial

Why clinical research needs medical audit

Clinical research is considered by many doctors as erudite and not an activity likely to involve them directly. Indeed, most medical practitioners are so distanced from clinical research that they do not consider entering patients into clinical trials. The reasons for this are unclear but may derive from attitudes acquired as undergraduates, when research is often perceived as unrelated to the "real" world of medical practice, but belonging to an elite world set apart from routine practice. On the contrary, if you take the view, as I do, that good clinical research is not only concerned with the innovation and evolution of new clinical interventions and treatments but is also the vehicle for the logical and measured introduction of new treatments and approaches to care into routine practice, then all practitioners have a clear role in the clinical research process.

As the basis of clinical research is clinical practice then there is a clear relation between medical audit and clinical research. The final step of a good clinical research programme will be medical audit as this provides a mechanism for ensuring that the results of research have been incorporated into clinical practice. Both research and audit activity need to involve all relevant practitioners at all stages of planning and implementation. The connection between clinical research and audit must be understood and exploited if audit is to make an impact on the quality of care not simply in units or individual hospitals but also at regional and at national level. Good audit is possible only when clinical interventions and innovations are based on good clinical evidence. Getting doctors (or anyone) to change practice is difficult. Clinical research has tended to progress without any clear policy on how practice is ultimately going to be modified.

As an academic haematologist with an interest in haematological malignancy it seems clear to me that medical audit is also important for facilitating clinical research as it is through the medical audit process that the quality of clinical care is assessed and compared with an agreed guideline. This connection between clinical research and audit is important; these are linked in series rather than in parallel. It is critical that the audit process feeds the next research ideas and that the evaluated results of well constructed research projects are the focus of the next audit. An example taken from the work of the haematologists in Northern region illustrates the natural dovetailing of research and audit and the importance of the facility for audits of some topics to be organised regionally.

Example from Northern Regional Haematology Group

During a medical audit/research meeting the following question was raised. Are clinicians in the Northern region identifying, investigating, and treating Hodgkin's disease appropriately by current standards? The approach taken to answer this question is as follows. A critical component of the audit will be assessing outcome and the use of accepted current practice of various treatments for given stages of Hodgkin's disease in

accordance with the generally accepted guidelines followed in the Northern region – for example, the use of radiotherapy alone for early stage disease, combined treatment for intermediate stage disease, and a standard intensive chemotherapy regimen for advanced stage disease. Other aspects of the audit include the accuracy of histopathological diagnosis and the time taken to complete staging procedures.

The first step is to communicate with all those clinicians who look after patients with Hodgkin's disease in the region, who will be the key participants of the audit. It is important that they have a role in developing and designing the audit, though the research team will take primary responsibility for activating the programme. The audit group needs to decide on the information required to answer the question set and to work out standard agreed proformas for collecting the necessary data relating to diagnosis, investigation, and treatment. For this audit both the histological and staging procedures need to be independently reviewed. Thus pathologists and radiologists will also be involved in the audit from the outset. Regular communication and contact with the participants is all important. The process needs a central audit-research coordinator and care has to be taken to ensure that the analysis is rigorous and the data are accurate. Thus data collection will need to continue long term so that the audit process can evolve and modifications to practice can be identified and reviewed again. There are certain financial implications, and funding agencies must understand that such groups will take time to develop and learn to work together. The investment is a sound one and likely to produce long term gain.

Discussion of results

The anonymised data are collected, collated, and analysed. The information derived is shown to the participants and compared with internal regional standards and standard approaches in the United Kingdom for the diagnosis, staging, and treatment for the different sub-groups of Hodgkin's disease.

This information has many uses. It provides individual units with information about their practice and indicates aspects of practice where care of patients with Hodgkin's disease does not meet current standards and where patients are getting less than the best available treatment. On reviewing the audit data it may become apparent that not all aspects of care outlined by the guidelines are considered ideal and these guidelines may need to be reviewed and form the basis of new research or audit approaches. Preliminary results in the Hodgkin's disease audit suggest that 10% of histopathological diagnosis will be modified and that there is a striking range of time taken to complete preliminary computed tomographic scan staging (4–26 weeks).

The experience of the Northern Regional Haematology Group in its attempt to formalise and organise a regional approach for managing each of the haematological malignancies shows that this process does not threaten individuals or hospitals. It is a way of

developing and agreeing workable treatment guidelines acceptable to all participants.

Relation of audit process with clinical research

The process of audit allows the dissemination of the findings of clinical research. New research findings about the treatment and assessment of treatment of Hodgkin's disease can be discussed in the light of current local practice and, when appropriate, incorporated into the guidelines. It seems likely that this approach will enable clinical research to have a greater effect on clinical practice and therefore on patient care than academic meetings because each participant has some ownership of the data and is able to compare local practice through locally generated data with that of other centres.

Furthermore, there is the opportunity for the results of audit to influence the clinical research agenda. Patients falling outside the parameters for known effective treatments or those not responding to standard treatments will provide the questions which are the basis for new clinical research studies.

It will also be possible to involve more clinicians in the process of clinical research. For example, a clinical prognostic index for patients with Hodgkin's disease designed to predict those patients unlikely to respond to conventional treatment has been produced within the Northern region and in Scotland.¹ Through the audit forum it was possible to agree that for patients at standard risk, defined by this index, a standard approach will continue, but that all those identified as being at high risk will have the opportunity to enter a Scotland and Newcastle Lymphoma Group clinical trial of the initial use of aggressive treatment followed by randomisation for further chemotherapy or auto-transplantation in the first remission.¹

Effect of purchasing on relation between audit and research

There is concern that competition and market forces might lessen the likelihood of the development of the integration of audit and research. In the Northern Regional Haematology Group we have found that our common goals, interest in our own specialty and the wellbeing of our patients, plus well developed trust and communication overrides any temptation of individuals to exclude themselves from the group. The attitude and determination of clinicians and their belief in the advantages of the model outlined are critical for the continuation of comparative audit. Contrary to initial fears, there has been considerable support from management at all levels to help to perpetuate our model and extend it to other disciplines. Once the audit process is under way it becomes extremely productive, and I encourage all practitioners, both in hospitals and in general practice, to join in and reap the benefits. In this way it is our patients who will undoubtedly gain the most.

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1 Proctor SJ, Taylor P, Mackie MJ, Donnan P, Boys R, Lennard A, *et al* with Members of the Scotland and Newcastle Lymphoma Group (SNLG) Therapy Working Party. A numerical prognostic index for clinical use in identification of poor-risk patients with Hodgkin's disease at diagnosis. *Leukemia and Lymphoma* 1992;7(suppl):17-20.