RESEARCH INTO PRACTICE .... PRACTICE INTO RESEARCH – REPORT OF THE DAY

BRIEF INTRODUCTION TO CLINICAL AUDIT
MRS LYNNE HILL, RCVS PRESIDENT

Clinical audit is something that many veterinary practitioners look on with fear, causing them "to break out in hot and cold sweats". But the concept should be embraced as a useful means of benchmarking professional standards today and one that will provide the data to help raise those standards tomorrow, RCVS president Mrs Lynne Hill told the meeting.

However, clinical audit was not something that existed in isolation, it was part of the broader process of clinical governance. This involved processes such as education and training, risk management, clinical effectiveness and R&D. It offered a means of gathering the information essential to provide an evidence base to justify the methods used in veterinary practice and a means for individual clinicians to measure their performance against their peers. Greater openness and a willingness to share clinical records with others was therefore a crucial element in the process.

One area in which clinical audit was already accepted as useful by veterinary practitioners was as a means of monitoring mortality - particularly anaesthetic deaths - and wound breakdowns. But its goals should be much wider, including even non clinical activities within a practice, such as communications with clients.

Indeed, the Royal College believed that clinical audit was so important to the future development of veterinary practice in Britain that it had been incorporated into the criteria that would be used to assess a practice's place within the different tiers of the practice standards scheme. Practices will be expected to set up the framework for clinical audit with appropriate records, checking of outcomes, written treatment protocols and regular updates of these policies.

Yet there were still significant question marks on whether practices have all the tools necessary to unlock the potential value of clinical audit. Certainly there were doubts over whether the clinical records maintained by most practices were both suitable and accessible, and whether many practices can spare the time for the necessary analysis. What was certain was that existing clinical records in practices around the country was a hugely valuable source of information on the efficacy of current methods and for the development of new techniques. "There is so much information out there sitting on computers and on card systems that is not being used and that seems to me an awful waste," she said.

SPEARHEADED COLLABORATION IN CLINICAL MEDICAL RESEARCH
DR LIAM O'TOOLE, UK CLINICAL RESEARCH COLLABORATION

For too long, clinical research in Britain has been carried out in an environment that is far from satisfactory. The necessary infrastructure has been under-funded and in decline, it has been working within a smothering bureaucracy and facing a shortage of new blood because of the lack of young clinicians prepared to make a career in research rather than providing medical services.

This rather gloomy assessment of the current outlook did not come from one of the veterinary speakers at the meeting but from the sole representative of the medical profession. Yet Dr Liam O'Toole's verdict on the situation within the NHS struck a chord with many of those in the audience working in the British veterinary school system.

As chief executive of the UK Clinical Research Collaboration, Dr O'Toole explained how his organisation is spearheading an attempt "to re-engineer the environment to make it easier for clinicians to do research as part of their normal service. This would change the way clinical research is conducted in the UK and by harnessing the power of the NHS, to establish the UK as world leader in clinical research."

The impetus for this initiative had come from the highest level and reflected the British government's recognition of the importance of the clinical trials industry to the health of the national economy. Without efforts to reorganise the research capabilities of the NHS, it was likely that the international healthcare companies which sponsor large scale trials would increasingly take their business abroad. Although the UK is still an attractive venue for research for other reasons, trial sponsors know that in countries like those in Eastern Europe, studies are less likely to undergo costly delays because of the failure of participating hospitals to meet their contracted patient recruitment rates, he said.

A model for what could be achieved already existed within the NHS in the form of the National Cancer Research Institute which had examined the funding and conduct of clinical trials in the oncology field. As a result, the UK recruitment rate for studies on new cancer treatments had doubled, resulting in significant cost savings for the trial sponsors and the faster introduction of new treatments.

The UK CRC was established with 82 million pounds of government funding to cover the cost of training programmes and develop the necessary enabling technologies, such as IT systems. This latter task had been a major issue, Dr O'Toole pointed out because of the variation in the methods for maintaining patient records in different parts of the NHS - "some electronic, some paper based and some using parchment".

With a headquarters staff of ten, the collaboration draws together all the stakeholders in the clinical research community, the various state and charitable bodies funding research, together with representatives of government, academic and industrial interests. Each of these partners was consulted but they did not have the rights to representation on the steering committee as this would have made the organisation far too unwieldy, he suggested.

The value of this lean decision making structure was evident from the fact that the collaboration was able to launch its training programme within one year of the first planning meeting. The new structure had only been properly established this year and so it was much too early to see whether it would achieve all its goals. But because of the goodwill of all participants some of the key projects necessary for the success of the initiative had already been completed and there was a great deal of optimism about its prospects.

HOW TO CREATE AN ENVIRONMENT IN WHICH CLINICAL ACTIVITIES CAN BE RESEARCH ACTIVITIES AS WELL

PROFESSOR JONATHAN ELLIOTT, ROYAL VETERINARY COLLEGE

How to create an environment in which clinical research may flourish within the veterinary schools was a similar concern addressed by Professor Jonathan Elliott, research vice-principal at the RVC. One of the major obstacles to conducting research alongside the teaching and clinical services duties of a university facility was its expense - as well as the lead researcher and associated clinicians there was a need for good back up staff in the form of nurses and technicians to ensure that the agreed protocols are followed. There was also a need to access the skills of scientists from other disciplines such as epidemiologists, statisticians, etc to ensure that the research project was asking the right questions.

In a busy university clinic there was always the potential for conflict between the clinician's research and his or other duties. To work effectively the researcher needed time to develop ideas and this was unlikely to happen if they spent more than 50 per cent of their time in clinics. So a researcher would need sympathetic colleagues who would not resent having to take on the bulk of the routine clinical services duties.

The patient population seen in a university referral centre could also be a problem when attempting to conduct good quality research - in many respects a first opinion practice was a much more satisfactory environment, he suggested. This was because first opinion practices had access to a much larger patient population, without the inevitable biases introduced by the referral process, which obviously favours highly motivated owners and well funded animals. There were also difficulties in carrying out longitudinal studies requiring follow up appointments if owners have travelled long distances for the referral.

Yet whatever the difficulties of conducting research in a veterinary hospital the RVC was attempting to overcome them by providing the best possible organisation and infrastructure. The school was developing a comprehensive electronic patient record system and a well organised sample archiving system, while also providing vital support for its clinical researchers, in the form of specialist clinical research nurses.

Critical mass was important if researchers were to have the time away from clinical duties in which to conduct their research. The RVC hospitals did have two or more staff to cope with the work in most clinical disciplines. Researchers also needed contact with non-clinicians with important complementary skills so the academic staff had now been reorganised into eight research groups combining both clinical and basic scientists.

Guidance for clinicians at the beginning of their research careers was particularly important in creating an ideal research environment. The school was developing a system of co-supervision of residents by both basic and clinical scientists. Meanwhile, it was also reorganising the programme of undergraduate elective research projects to run throughout the academic year, to spread the availability of clinical cases and allow better access to patients with seasonal conditions.

INVOLVING PRACTITIONERS IN RESEARCH
DR JAMES WOOD, CAMBRIDGE INFECTIOUS DISEASE CONSORTIUM

Giving veterinary practitioners the skills they will need to conduct research alongside their normal clinical duties is one of the key goals of the Cambridge Infectious Diseases Consortium, as described by its director Dr James Wood.

The consortium, established in January 2005, and funded through the DEFRA-backed Veterinary Training and Research Initiative, will be conducting research collaborations and providing training in infectious disease control for both undergraduates and postgraduate research fellows. But its programme of one-week residential training courses for practitioners had proved an immediate success with 12 clinicians attending the first course and 18 already signed up for the second. The good attendance at these two courses demonstrated that there was huge enthusiasm within the practitioner arm of the profession to get more involved in research, he said.

These courses consisted of four or five daily lectures and course work in the evenings. By the end of the week the practitioner would be expected to have submitted a formal proposal for a research project which would be taken back to the practice and worked on over the following 12 months or so. By the end of that period they would be expected to have prepared a paper suitable for publication in the scientific press.

Courses included training in core skills such as statistics, literature searches and scientific writing. CIDC staff would also provide ongoing guidance when the practitioner returns home and there was scope for some financial support for laboratory fees, etc.
Advice from more experienced clinical researchers was valuable at all stages of the process but particularly during the planning phase. Without this help clinicians were likely to make unwise choices on the goals for their project which was likely to address issues "that are too big, unanswerable or entirely descriptive", he said. Overall, however, these courses were genuinely a 'win-win' situation, fulfilling the sponsor's goal of creating a cadre of research savvy vets and giving the practitioner a full year's CPD allowance and the intellectual stimulation that was occasionally missing from routine practice work, he said.

As an experienced veterinary epidemiologist, Dr Wood said he had been involved in a number of large scale projects carried out almost exclusively in the practice setting. These included recent studies of anaesthetic deaths in horses and on post vaccination adverse events in dogs. These demonstrated that there were no insurmountable barriers to practice-based research but there were issues that needed to be addressed if the planned network of practitioner-researchers is to be sustained. It would be a major challenge to maintain the training system and develop a suitable long term career structure when the current funding runs out, he suggested.

PRACTICE BASED POPULATION STUDIES
DR HUGH LEWIS, DATASAVANT/BANFIELD

Once the proper infrastructure and funding are secured, however, high quality research can be readily carried out using the information collected by first opinion practice, US-based veterinary surgeon Hugh Lewis told the meeting.

Dr Lewis is a Glasgow graduate who is president of the US clinical data company DataSavant. This was established by the Banfield hospital group to analyse the clinical records of the animals treated within its 500 member practices. This is the biggest US corporate practice with hospitals set within Petsmart superstores in 43 US states, and with its first two UK practices now opened in Leeds and Manchester.

The group maintains clinical data on 20 million cats and dogs and with up to 80,000 new records added each week. The group's philosophy was to provide as far as possible identical treatment by each one of the 1000 plus clinicians working in the group, so each hospital was designed to be the same, offering the same lay out, equipment and clinical protocols, he said.

The computer software was also identical in each practice and all data was downloaded to a single data warehouse at the end of each day. This data provided an invaluable resource both for the Banfield group and the wider veterinary profession, Dr Lewis explained.

Although the clinical protocols used within the group were intended to be identical they were certainly not static and would be updated whenever new evidence emerged on improved diagnostic or therapeutic techniques. DataSavant's role was to data mine the information produced by member practices and extract clinically useful information. "Our job is to generate new understanding and feed that back into our own practices through upgrading their protocols and procedures but we will also be publishing and sharing that data with the rest of the profession," he said.

The information generated by comparing the experience of some many clinicians was particularly useful in identifying items of accepted wisdom that were no longer true. The group's broad geographical coverage had enabled it to compile an atlas of diseases found across the USA. He described a letter received from a member of the State veterinary board in one US state criticising Banfield's policy of providing prophylactic treatment against heartworm in dogs. He responded by pointing out that the group's clinical records confirmed that the parasite had now spread to that state and so the treatment was not 'unethical' as claimed but was now very necessary.

As a result of Banfield's strong emphasis on preventive medicine, the database contained considerable amounts of information on healthy animals. This was likely to be useful in the organisation and analysis of prospective studies, he said.

The company was also aware of its wider obligations, Dr Lewis said. It was collaborating with the US Centers for Disease Control in an investigation across the USA into the prevalence of the pathogens responsible for major tick-borne conditions, such as Lyme disease and ehrlichiosis. Meanwhile, the group's management appreciated the need for this sort of original research to be properly funded and had decreed that 50 cents from every single consultation taking place within its hospitals would be diverted to a research fund.

ROLE OF PRACTITIONERS IN SURVEILLANCE AND HOW IT FEEDS BACK INTO HERD HEALTH PLANNING AND DISEASE CONTROL

MR GEORGE GUNN, SAC ANIMAL HEALTH GROUP

Veterinary practitioners have an even longer established role in researching the conditions affecting farm animal species. But as George Gunn of the Scottish Agricultural College's animal health group in Inverness pointed out the coverage was incomplete. The UK veterinary profession was very effective in identifying and monitoring exotic and emerging diseases but had little information to hand on the prevalence of endemic disease.

He described the history of worthy but ultimately unsuccessful attempts to correct this imbalance in Scotland during the early 1990s with the development of health assurance schemes which included health planning. The primary aim of the scheme was commercial in attempting to optimise farm incomes through the minimisation of losses due to endemic diseases such as bovine viral diarrhoea, infectious bovine rhinotracheitis, Johne's disease and leptospirosis. At the time, farmers were also optimistic about the prospect of receiving a premium on cattle sales.

The initiative would also have created a database that would have provided a means of benchmarking disease prevalence and collected data that could be used for research purposes in the validation of decisions on disease control options.

However, the timing was unfortunate as the farming unions revised their priorities in the wake of the BSE epidemic and there were some unwise choices made as to the appropriate means of data storage. He also noted that the project had demonstrated the deficiencies in farmers' ability to record those details that were not directly relevant to the EU subsidy process.

Nevertheless, the exercise had shown the potential of a properly managed quality assurance scheme to generate useful data on endemic disease patterns. But if the concept was to be re-examined it would be necessary for the farm health records to be much more comprehensive and farmers needed to collaborate with each other more effectively to achieve their shared goals.

EXPERIENCE AS A PRACTITIONER OF PERFORMING RESEARCH IN A PRACTICE ENVIRONMENT

MR DAVID BLACK, PRACTITIONER IN CUMBRIA

So far in the meeting, all the initiatives discussed for stimulating research by practitioners had been 'top down' actions organised by larger organisations. But veterinary surgeons in practice are just as likely to become involved through a 'bottom up' process that they initiate themselves, noted Mr David Black, managing director of the Paragon Veterinary Group in Carlisle.

While there were some hurdles to be overcome, it was realistic to expect general practitioners to be able to carry out useful research as well as providing a service to clients. Indeed, in some respects, research was just a logical extension of a practitioner's normal clinical curiosity. There have been many examples of important developments achieved

through rigorous clinical investigations carried out by ordinary practitioners, notably the identification of diseases like BSE. Good science was at the core of any veterinary surgeon's methods and Mr Black expressed irritation with the way vets are often characterised in the media as being somehow outwith the scientific mainstream.

The veterinary practitioner's 'need to know' when attempting to deal with a clinical problem was one of the many factors that made practice-based research a good alternative to institutional studies. Another asset was a result of the practical nature of the questions that practitioners needed to ask - "they are dealing with real animals on real farms in the real world," he said.

As earlier speakers had noted, the clinical data accumulated by practitioners was potentially a huge resource. Practitioners were able to carry out highly valuable field research, were largely apolitical and were relatively inexpensive to employ for this work. Moreover, they came with a cadre of enthusiastic research assistants, their farmer and pet owning clients who were often prepared to go to great lengths to help if told that their animals were needed for a research project.

In human medicine, it is estimated that only about 20 per cent of the procedures used are evidence-based, in having been rigorously tested in full clinical trials. How much lower was the figure likely to be in the veterinary field?, he asked. Efforts should be made to establish a better scientific basis for the methods used in practice and given the shortage of funding and manpower in the universities, much of the responsibility must fall on practitioners.

However, there were some important issues to be addressed. It would be impractical, for practitioners to try and achieve the research gold standard of placebo-controlled, double-blinded trials because it would be unethical to deliberately withhold treatment for a client's animal. So scientific journals must accept that practice based studies would usually need to be designed as three-way comparator studies even though these have much less statistical power. Furthermore, journals must appreciate that practitioners face major problems in steering a course between methods that are novel enough to be worthy of publishing and techniques that are so unproven that they become irresponsible.

These issues were perhaps part of the reason for a further obstacle faced by practitioners in attempting to get their work published. Mr Black believed that too many academic researchers looked down on their practitioner colleagues and assumed that any study conducted in practice would automatically have less scientific value than an academic project. Collaborations between academic staff and practitioners were the obvious way forward in overcoming these problems and could make better use of both side's skills.

DISCUSSION SESSION

An ability to work closely with practitioners has been crucial to the successes of the Veterinary Laboratories Agency in monitoring exotic and emerging diseases for many years, noted Graham David, the agency's endemic diseases programme manager. It was keen to extend this relationship by establishing a network of sentinel practices around the country that would provide the clinicians needed in the field to strengthen this work.

Dr David believed that veterinary practices should look on their research partnerships with government, the animal health industry and others as a core part of its business activities. But it was essential that practitioners were treated as a key part of the team planning the research and not simply as a service provider. "A large group of practices is an immensely useful resource but they will have to be part of the project planning process. They have to consent to the procedures, agree the remuneration and agree the deadlines for the production of data. For practices these are business decisions and research should be seen as another part of the income stream."

However, concentrating on the larger and better equipped practices may not always be necessary for the success of a project, according to Professor Sandy Love of the Glasgow veterinary school. He believed that small practices are often those that work hardest to recruit cases into a trial and to follow the trial protocols most assiduously. He recalled carrying out an epidemiological study on equine colic which produced the surprising finding that the condition was unknown in the Newmarket area, as none of the large specialist practices in the town had submitted case details.

In long term studies, Dr Wood warned that it was inevitable that some clients would lose interest in the project and would no longer be prepared to help the research team. So it was necessary to anticipate these losses in the study design and ensure that the final population was large enough to have statistical power. He agreed with Dr David that some practitioners would find financial rewards an incentive to take part in a project but he believed that many other practitioners found participating in a research project incentive enough.

Responding to a point made by Mr Black, Mr David Anderson of the Home Office Inspectorate reassured colleagues that studies carried out in a practice setting were unlikely to require a license under the Animals (Scientific Procedures) Act. Any procedures carried out in the course of routine veterinary work were exempt under this legislation. But he urged any practitioner with concerns about the legality of any proposed study to contact their local inspector for advice.

One of the enduring problems facing anyone wanting to carry out research on companion animal species was the shortage of funding, observed Chris Little, a former academic now in practice in Canterbury. One sector where colleagues might consider looking for grants was the human medical charities. In diseases such as diabetes and hyperthyroidism the growth in the human population with the disease had been accompanied by a surge in the numbers of cats and dogs affected. He suggested that comparative studies into the shared environmental factors responsible for these trends might benefit all species.

Dr Dominic Mellor of the Animal Production and Public Health Department at Glasgow pointed out an area in which companion animal researchers were less fortunate than their farm animal colleagues. He said there were no really reliable current figures on the numbers of cats and dogs in this country and so it was impossible to carry out the most basic calculations of the population at risk to a particular condition.

Norfolk practitioner Mrs Carole Clarke believed that this information was certainly available on practice clinical records. However, few practitioners would have the technical knowledge necessary to extract the information in a usable form. Therefore, developing the

skills to obtain and analyse data that was crucial to the development of new veterinary treatments must be a joint responsibility of the practising and academic arms of the profession.