The Swedish system of ethical commitees in the laboratory animals field

by ERNST BÁRÁNY, M.D.

Sweden has had a general law for the protection of animals for many years but research was at least partly shielded by special paragraphs. This is still so, but a system of ethical committees has been developed for the sake of the animasl but also that of the research workers. I shall try shortly to tell the story of the ethical committees and discuss the experience collected in the first three years of their full scale activity.

The Swedish Medical Research Council formed a Laboratory Animals Board in 1965. It contained a few members of the Medical Research Council but encompassed many specialist and user categories. The anti-vivisectionist movement was only a distant rumble at the time and there was no outside pressure on the Board to do anything special to protect laboratory animals. But within the Board, the neurophysiologist Sven Landgren, who is a veterinarian, always brought up the ethical problems. We tried to do our duty by organizing courses and demonstrations and by writing a Swedish Language manual, a junior UFAW handbook. Thus our attention in the ethical field was mainly directed towards improving the lot of the animals by improving the knowledge in the animal house as well as in the laboratory. In 1972, the Medical Research Council asked the Board to function as an ethical committee for those grant applications which somebody in a review committee of the Council had found dubious from an ethical point of view. We handled a very few of these. Evidently the review committees felt they could do without us. We also offered our services to other granting bodies but never were asked to help. After three years of this the Medical Research Council asked the Board to suggest a system by which the Council administration could automatically decide whether or not a grant application involving the use of animals ought to be referred for special ethical consideration and how this scrutinity was to be organized. We suggested the formation of *regional ethical committees* based on the different universities, charged with looking at grant applications to the Medical Research Council arising from that region. This would make it possible for the committee to talk to the applicant. Our proposal for selecting applications which needed to be looked at from an ethical point of view was based on *a scale of expected discomfort* for the animals. It would be the responsibility of the Medical Research Council to decide above which level of discomfort experiments must be submitted to ethical scrutinity before they were funded. The scale of discomfort was modelled on another kind of discomfort, viz. the scale of fees a patient

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Table I

The original scale of discomfort

Category	*Examples* (not exhaustive)
1. All the experiments planned entail interventions causing little pain or no interventions at all.	Injections, blood sampling, gavage, simple diet experiments, breeding experiments, behavioural experiments without important surgical intervention or restraint.
2. All experiments planned will be done on anaesthetized animals that will not be allowed to wake up again or on animals that will be painlessly killed without anaesthesia.	Blood pressure experiments, removal of organs for historical or biochemical investigation or for experiments on surviving organs or tissues.
3. In some of the planned experiments an intervention will be made under anaesthesia but the animal wille be allowed to wake up. The character of the intervention is, however, such that — if it had been done in a therapeutic situation — it would not have been deemed to cause considerable postoperative pain.	Biopsies, cutting down on vessels, placement of chronic cannulas, gonadectomy, hypophysectomy in small rodents by standard techniques, simple lesion experiments in the nervous system.
4. Same as 3 but the postoperative reaction can be expect to be severe.	Large surgical interventions, thermal burns.
5. Experiments are planned for unanaesthetized animals which may become seriously ill following the treatment or suffer considerable pain.	Toxicity tests, radiation illness, certain infections and tumour transplantations, stress-, shock- or burn-experiments, experiments entailing suprathreshold pain, behavioural experiments with severe restraints.
6. Experiments are planned in unanaesthetized, immobilized animals, immobilization being by curare or corresponding drugs.	Certain physiological and pharmacological experiments on the nervous system.

once had to pay for minor surgical interventions in the public health care system. Since one could not in advance stipulate a fee exactly appropriate for every possible surgical intervention one selected a number of standard examples, decided on fees for these and let the surgeon charge the patient according to the standard example most close to what had actually been done. Table I.

While this went on at the MRC level, my physiologist colleague Professor Karl-Johan Öbrink already had

started the preparations for a local ethical committee in the laboratory animals field at Uppsala. It was therefore quite natural for the Medical Research Council to turn to the Uppsala Medical Faculty for co-operation in what was in fact an administrative experiment. The nascent local ethical committee formed a small *ad hoc* group to deal with the grant applications to the Medical Research Council. The Council had decided that the first two categories where discomfort was negligible, were not to be reviewed. We looked at the applications and talked to all the relevant applicants. This was very time consuming for all. It was quite evident that if we were to look at for instance the pharmaceutical industry or people funded from other sources, the system was impossible to generalize.

The solution was inherent in the Öbrink plan for the local committee. The key parts of his idea were:

1. There would be members of the committee within easy reach of anybody planning animal work, even if the committee had to be very large.
2. The committe would contain not only research workers but also animal technicians and laymen.
3. The day to day work of the committee would be done by subcommittees formed *ad hoc* whenever somebody wanted to start a new type or set of experiments. The experimenter would select a suitable member of the ethical committee (one hopefully understanding the planned experiments) this committee member then would collect a very small subcommittee around him to deal with the specific application 'Dealing' implied discussion with the applicant.
4. An important aim of Öbrink's was to keep paper work and delay to a minimum. The decisions of the subcommittee might or might not be ratified by the full ethical committee, meeting at long intervals, but if the subcommittee had approved, the experiments could start right away.
5. In order to preserve the confidence of our colleague, the ethical committee should be only advisory and have no power, legal or administrative.
6 One important Öbrink idea was that by having the researcher discuss his projected animal experiments with an independent colleague and other members of the subcommittee, the general ethical awareness in the research community would increase.

The first ethical committee at Uppsala was hand-picked by Öbrink and Lars Wass, the key laboratory animals person in the Swedish university administration. It consisted of about 30 people. Research workers were in the majority. In order to educate ourselves, we had frequent meetings to which applicants were invited and we discussed individual applications in full committee. We learned a lot from the early work. The main lesson was that as far as animal protection goes, the research worker members could do much more than laymen or technical personnel to prevent unnecessary suffering. We could suggest modifications of the protocol, which were taken seriously by the applicant.

While we were still trying to work

out an effective system, a new government came into power in the fall of 1976. The Minister of agriculture, under whom animal protection belongs, was an antivivisectionist and had promised to do something quickly. And, since we had a system working at Uppsala, even if it was in its infancy, the government decided that the Öbrink system with slight modifications was to be introduced all over the country. This is how Sweden got a system which had originated within the research community and which we could live with straight from the start. It was an unexpected stroke of luck which, however, also implied that the system still was at an experimental stage and it has in fact been modified repeatedly even during the first few years of life which are the ones I am reporting on.

The ethical committees are only advisory. How then can they have an influence? The Government authority ultimately responsible for animal protection in Sweden is the National Board of Agriculture. Its regional veterinary officers supervise the local public health inspectorate which inspects animal quarters but also has the duty to take action against animal abuse, if necessary in conjunction with the regional veterinary officer or the police.

Since the ethical committee is only advisory, the authorities are not bound to accept its opinion but until now it has never happened that they have taken steps against anybody for an animal project which was accepted by the ethical committee. If the ethical committee advises the researcher to refrain from an experiment, he can still perform it and

Table II

Composition of the ethical committees

Six Regional Boards of Higher Education (mixed university and political bodies)

propose

research workers
technicians
laymen

Major animal protection groups in the 6 university regions

propose

laymen

Central Veterinary Bureau of National Board of Agriculture selects and appoints

One special ethical committee for military research

6 regional ethical committtees with their chairmen and vice chairmen

6 regional subcommittees for secret projects

the committee will not inform on him. But he runs the risk of being caught out by the authorities because they have access to the protocols of the ethical committee. Thus, submitting the project to an ethical committee and have it accepted protects the animals against abuse but also, at least partly, shields the researcher against the authorities.

It is evident that the composition of the ethical committees is of the utmost importance. The members of the different committees (no longer local but only one for each university region) are appointed by a Central Veterinary Bureau[1] which asks for lists of suitable people from different sides. Table II shows how this is done.

An ethical committee consists of equal numbers of research workers, technicians and laymen. All of the research workers and technicians and half of the laymen come from the lists submitted by the Regional Board of Higher Education. The remaining half of the laymen comes from lists prepared by the major animal protection groups. The Veterinary Bureau has the authority to select the members without having to explain why some are rejected. In the case of researchers and technicians, they have difficulties in finding sufficient numbers of candidates. Also the 50% of laymen to be suggested by regional boards of higher education are not easy to find. The animal protection groups of course are anxious to be represented. During the first 3 years, the veterinary bureau passed over nominations from the rabid antivivisectionists. Since, however, a person can be a rabid antivivisectionist but an efficient memger also of a more moderate group, one of the leading radical antivivisectionists was put onto one of the committees. This caused a lot of trouble.

Table III

Research workers on Uppsala committee 1982

2	Academic Hospital
3	Biomedical Centre
3	Agricultural and Veterinary College
1	Zoophysiological Institute
1	Psychological Institute
1	Local drug company Pharmacia
1	Government Food Administration
1	Government Drug Administration

The researchers on the committee are selected so as to be easily available in all institutions where animal experiments are performed. Table III shows the distribution in the Uppsala region just to show the spread. (A considerable amount of arm-twisting was necessary to recruite active research workers for committee work!) The technicians also are taken from a wide spectrum of institutes. Half of them are laboratory technicians, the other animal house technicians.

The laymen proposed by the Board of Higher Education are supposed to represent the unbiased public opinion. They often are retired local politicians, professors of ethics at the University and such like. After a few years on the committee, they become so well informed that they can put embarassing questions. There is of course nothing to prevent members

[1] The name and address of this specific Bureau are: General Veterinary Division of the National Board of Agriculture, S-551 83 Jönköping, Sweden.

of animal protection groups to be proposed as laymen by the Regional Boards of Higher Education if they had been put forfard for instance by political parties.

All members of a committee are bound by the general secrecy laws. Noteheless, special secrecy arrangements have been made for military research and, where desired by the company, for drug company research. Nobody is paid for work on the committee but one is reimbursed for travel costs. Meetings are during working hours. The full committee meets at least twice a year. Extra meetings can be held. Once a year the chairman and selected members are collected by the Central Veterinary Bureau for discussion.

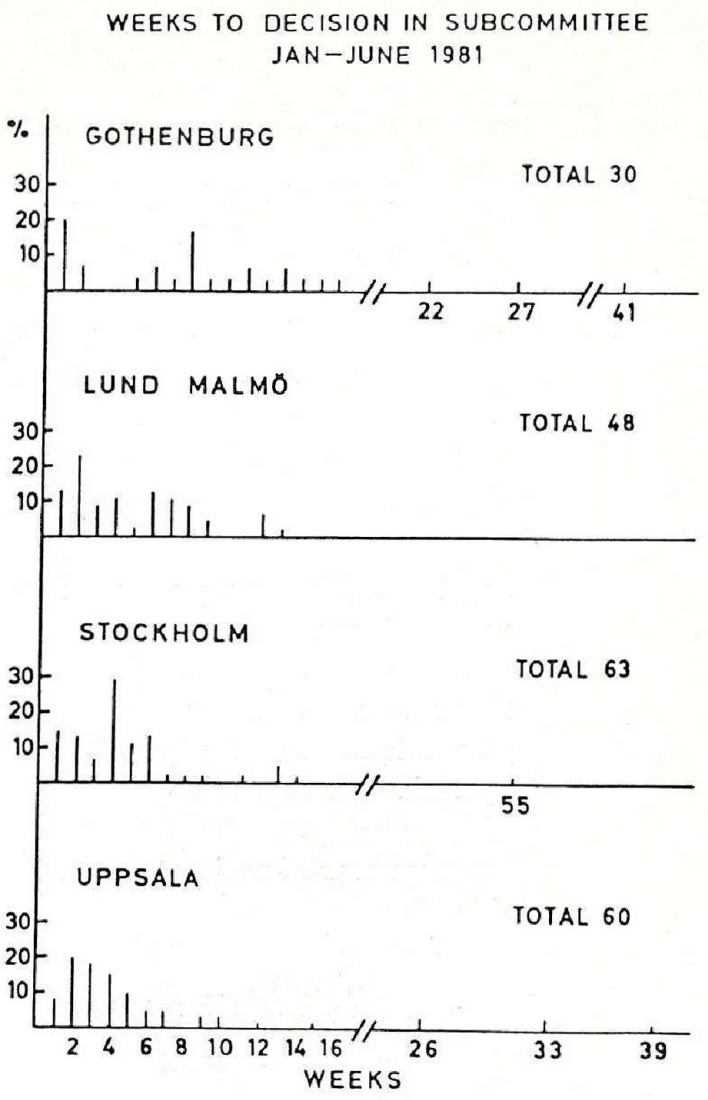
According to Öbrink's ideas, the day to day work is done by subcommittees. Such a committee consists of, at least, a research worker on the ethical committee, a technician and a layman. It very soon was found that antivivisectionist laymen never were asked to take part in the subcommittee work. Therefore we now have rotation lists for the laymen and the tehcnicians. Each research worker on the committee has a small number of laymen and technicians with which he is supposed to work and he is forced to call upon them a roughly equal number of times so that the load is evenly distributed among them.

The applicant submits his project on a one-page form, stating the aim of the research project, a short description of the experiments emphasizing what happens to the animals, the number of animals of different species and the number of animals falling into various discomfort categories (the 2 lowest discomfort categories are not submitted to ethical committees). He further has to describe shortly what kind of postoperative care the animals will have and what he plans to do to alleviate and abbriviate their suffering. He sends the form to the selected research worker on the ethical committee, this latter may ask for clarification but then asks a layman and a technician from the rotation list, they all read copies of the application and then meet with the applicant. After a discussion with the applicant, they quite often suggest improvements in his description of the procedure, much more rarely they suggest a modification of the procedure itself or a reduction in the number of animals. If the subcommittee agrees to the proposals of the applicant, they sign the form and the form is sent to the Central Veterinary Bureau. The applicant can then start work immediately. The Central Veterinary Bureau distributes the form to all members of the regional ethical committee and also to the local and regional authorities charged with animal protection.

A permission to do an experiment is valid for three years. Since very few experimenters can foresee exactly how many animals they are going to use, they tend to keep a safety margin on the number of animals. This had the deplorable consequence that we have no statistics of how many animals in fact have been used in the different discomfort categories, only the number projected by the applicants.

If an applicant or a subcommittee member disagrees with the verdict of a subcommittee, the matter is re-

ferred to the full committee. If necessary, an extra session of the full committee can be called. This has never happened to my knowledge. At the meetings of the full committee, all the verdicts of the subcommittees are reviewed and members of the full committee are encouraged to ask questions and discuss the verdicts. This is not very successful because there are too many verdicts to consider for a fruitful discussion at short notice. We have not been able to make the members study the verdicts well before hand and ask for explanations from the researchers or the subcommittees before the meeting. Thus the main responsibility rests squarely on the subcommittee. How cumbersome is all this? How much time does it take? If one is engaged on a project, one as a rule has a permission valid for 3 years and one has a certain amount of leeway as long as one does not conduct experiments that are more severe than the ones planned when the per-



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mission was given. So if one is lucky and can keep to the track, one has to apply for ethical scrutinity not more than once every three years. But even if the project is a new one, one can get it scrutinized within a few weeks as a rule, Fig. 1. From my experience the two main obstacles to a quick decision are: 1. the difficulty to agree on a time for a meeting between a busy politician and a busy clinician and 2. the inability of the applicants to use simple enough language. We insist on language which can be understood by the technical personnel and the laymen of the full committee. This is the main reason why forms are returned to the applicant for clarification. Sometimes of course we have substantive doubts about an application and that can delay the green light. But on the whole the work of the subcommittees is reasonably fast and causes little difficulty. What about trade secrets or secrets of another type? With a large committee, leaks of course could occur. Therefore there is a small subcommittee dealing with applications for which secrecy of a higher degree has been asked for. As Uppsala we have had very few such applications, in other regions industry has asked for secret treatment of most of its applications. At Uppsala we do not require that industry disclose more than the code number for a compound it wants to test or work with. That may be the reason.

The plenary sessions of the committee have problems of their own. It is very difficult to collect a sufficient number of members, the statutory requirement is half the committee + one. An antivivisectionist lady in Gothenburg has caused trouble by prolonging the meetings until people had to leave and by frequent asking for shelving. This has caused clinical members of the committee who have other work to do, to refuse to take on an appointment for a second period and this of course is the main problem: how to make a large number of first rate people spend their valuable time on a thankless task in the face of sabotage.

In a new statute that went into effect in the fall of 1982 the Veterinary Bureau has tried to reduce the time lag by two measures. The subcommittee *must* give its verdict within three weeks and, in order to reduce fruitless discussion, the grouping of experiments into categories has been abolished. Either an experiment needs ethical scrutinity or it doesn't and then is doesn't come to the committee. We shall see if the system works better this way. On the whole, we have adapted quite happily to it, even if it goes against the grain to ask for ethical scrutinity of a preliminary experiment which you don't know if it ever will be repeated.

I should like to end by returning briefly to the scale of discomfort. Table I of course is only a rough prototype. In my view, however, it would be highly desirable from the Research Defense point of view to be able to show the number of animals subjected to experiments causing appreciable suffering. The principle of Table I could perhaps be utilized in constructing statistics of this kind.