

## Thought before action - What do the public and others really want to know?

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### Abstract

A number of frameworks, some set out in legislation, have been devised to prospectively or retrospectively report on animal welfare assessments in the context of the use of animals for experimental and other scientific purposes. In some cases these primarily inform the decision-making process when it is decided whether and on what terms animal use should be approved or when work is in progress (to compare expectations with reality); or, after studies have been completed, to compare expectations with reality looking for insights into good practice and lessons learned. No current information requirement system is ideally suited to all of these purposes, and care needs to be taken in reviewing the scope, limitations and benefits of the systems that are in use when looking for insights into true animal welfare costs. A failure to appreciate the distinctions between, and limitations of, various sets of recorded information results in the information that is available being misunderstood or abused, resulting in ill-informed formulated policies, imperfect decision making, and a poor public understanding of issues about which there is legitimate public interest. This paper explores the general principles that underpin information gathering frameworks and discusses their impact and uses in practice. It is argued that the starting point for any information gathering and reporting system must be the insights the information must support, and the audience for which it is intended.

**Keywords:** animal welfare, statistics, information requirements, severity assessments

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### Introduction

There is much misinformation and limited number of authoritative sources (Home Office 2007, European Commission 2007) of information on the nature, scale and consequences of the use of animals for experimental and other scientific purposes. Some of these systems provide only prospective estimates of anticipated animal welfare costs (Home Office (2) 2007, FELASA 2005) and thus only prospective severity assessments.

It is more difficult to find reliable collated information on the actual welfare costs encountered in practice, and it does not improve the public's understanding to present prospective estimates (which are often premised on the worst possible case, even when the worst effects might not be seen in practice) in a way where it is mistaken for what routinely happens in practice. For example, in the UK severity limits are assigned to individual protocols based upon the expected worst case in welfare terms: this level of suffering might have a very low incidence, indeed might never be seen in practice, and it not normally representative of what the animals used will typically

experience (APC, 1997).

Serious consideration is being given in many places to how meaningful information of actual welfare costs can be captured in a proportionate manner, and how it can be clearly presented in a timely manner (along with information on the benefits of the animal use – something which often cannot be judged objectively for some time after the animal use has been completed) to inform decision making, local practices, and the public debate.

In this paper I will argue that:

- the intended end-use of published information (the audience and the decisions and insights it must support) is the starting point when scoping information requirements and preparing material for publication;
- assessment of proposals, regulatory authorisation, and setting limits on justifiable animal suffering requires one framework and data-set;
- managing studies in progress requires another data-set;
- better informing the public's understanding and

resulting level of public debate required yet another data-set; and

- it is difficult to envisage or define a single, proportionate or manageable framework ideally suited to simultaneously satisfy these different needs.

### **Purpose is the starting point**

When prospectively evaluating proposals for animal use judgment with respect to scientific validity, likely animal welfare costs, and potential benefits must be exercised before the animal use begins using information which are effectively pre-study estimates of what is expected to happen in practice. Much of the information required and provided for these purposes, particularly if what is authorised is to be clearly defined, is of a highly-detailed technical nature – written by experts to be assessed by experts (notwithstanding that in many places some of this information may also at some stage need to be presented in a way that is accessible to lay participants) – and the required degrees of scrutiny and due diligence can only be properly applied by those with the necessary expertise. This is particularly true when finely nuanced protocol variations have to be evaluated to determine those which best meet the scientific objectives at the lowest anticipated animal welfare cost. Especial care also has to be taken when considering whether the information available pre-study about anticipated animal welfare costs is based on experience or is purely theoretical; and whether it is presented as the average, the range, or extremes of what might be seen in practice.

In contrast, the information best suited to informing the public's understanding should be in plain-English, perhaps as case-studies rather than detailed technical protocols, and if possible describing what actually happens in practice (not just what is done to the animals and what might happen, but what the actual welfare costs were).

For practical purposes many of the public's concerns can be distilled down to is animal use necessary and justified, it impartially and effectively regulated, and what do the animals actually experience and suffer?

### **Severity assessments**

There are a number of recognised severity assessment systems in use as means of estimating and categorising the likely welfare costs of programmes, projects, protocols, studies, study groups, or individual animals (Nuffield Council, 2006).

Some are aimed at informing decisions as to whether and on what terms animal use should be approved, and others are better suited to controlling welfare costs in practice once animal use is underway. In all cases additional information, not available at

the time requests for animal use are considered, is required if the lessons learned in practice are to be used to improve operational and future decisions and the managements of subsequent animal studies.

A number of people have an interest in indicative or real animal welfare costs. This information informs national policy and regulatory decisions. It can be used at local level to inform policies, decisions and practices. It is something that is required if there is to be a better informed public understanding and better informed public debate of the issues animal use for these purposes raises. However, when we look in more detail in each case at what information is required, when it is required, and how it is presented it becomes clear that in each case the information requirement is different in terms of when it is required, what is required, and in what format it is required.

### **Why is animal welfare information requested or required?**

#### **Prospective information**

I have set out above the main reasons for the need for prospective information about the likely welfare costs and potential benefits of animal use. However, as science is about doubts and uncertainties, what happens in practice is not always what was expected at the outset regardless of how good the planning and decision making processes were. In particular, in the context of animal welfare costs, in the absence of experience and real-data it can be difficult to extrapolate from hazards (what in theory might happen) and risk (what are the chances of these things happening and what will their significance be). As only prospective information is generally available to inform pre-study decision making, any effective regulatory system must build-in additional later checks and balances to ensure that the outcomes seen in practice are used to challenge the original suppositions and decisions. In addition, as a regulator, I am aware that outcomes are also heavily reliant on the competence and culture of care of the places and people who undertake the animal research if any mismatch between expectations and reality are to be quickly spotted and, if necessary, remedied.

At the authorisation stage the UK system (Home Office (2), 2007) uses the available prospective information to set severity limits for individual protocols (based on the worst expected/justifiable outcomes and setting this as the limit of acceptable suffering) and severity bands for projects (determining the amount of suffering that it is expected that the animals will typically experience). Both of these measures have serious limits in informing the public debate (a reflection on the fact that this is not what they were originally intended to do): severity limits of protocols paint a wholly misleading picture of the

suffering that will actually be experienced by the animals used: the severity bands for licences remedies this, but is it a relatively large-scale indicator giving no insight in the range of welfare outcomes that will be seen in practice.

### **Real-time information**

During the course of animal experiments real-time information on the actual welfare costs becomes available and can be used to inform decisions about individual animals, project management, and to challenge the original assumptions and review the earlier decisions.

Although real-time information should be accurate and timely, it is generally captured in a format that best suits local operational needs. Positive reporting is in many cases the norm (a comment not a criticism), and short-hand and technical terms abound. It tends to be highly context-specific, and not generally applicable to a wider range of studies locally or nationally unless and until it can be aggregated with other similar data and further processed. It needs to be remembered that this additional processing, whilst it can only be done at local level, tends to produce processed information more of interest to others rather than those whose resource is required to do the processing.

A further limitation is that real-time information is often essentially local operational information: it is generally neither widely-disseminated nor published.

### **Retrospective information**

Many systems appreciate the benefits that derive from documenting, collating and reviewing animal welfare outcomes when studies are completed. Such information can be used to challenge and improve project planning, decision making, and project management. It is also of interest to those involved in policy formulation. Last, but by no means least, this record of what actually happened in practice can, as the information is processed, be used to produce summary material in a range of formats well-suited to informing the public of what has actually happened in practice.

Again, in many instances the actual processing has to be done by those who will not see themselves as the primary beneficiaries.

### **The United Kingdom systems**

In the United Kingdom the use of protected animals for experimental and other scientific procedures is regulated by the Animals (Scientific Procedures) Act 1986: this implements the requirements of Directive 86/609/EEC and Council of Europe Convention ETS 123. The 1986 Act requires and makes use of prospective, real-time and retrospective information for a range of purposes.

Individual programmes of work are authorised by project licences, and inevitably project licence applications present prospective information with respect to both the potential benefits and the likely animal welfare costs. The application form captures highly-technical information for assessment by specialist inspectors who are all either medical or veterinary graduates. This information is then used to assign severity limits to the individual protocols (unclassified, mild, moderate or substantial) based on the worst justified welfare outcome expected to be seen in practice. It is then used to assign a severity limit to the project (again unclassified, mild, moderate or substantial) reflecting the level of suffering animals used on the project will typically experience.

The same information is also factored into a statutory cost-benefit assessment (APC, 1997), highlighting issues needing particularly detailed scrutiny, to determine whether and what terms the animal use should be approved.

In addition applicants are also invited to provide non-technical, plain-English abstracts of their proposals to be displayed at the Home Office website. Although this is a voluntary scheme over 80% of applicants supply this information, and over 1,000 are now displayed at the Home Office website (Home Office (3), 2007).

All project licence holders are required to maintain real-time records relating to the work undertaken and the findings in practice. In addition to this information being available to the regulator it is also of immediate interest to those undertaking the animal work, those who supply advice and support with respect to animal care and welfare, and local ethical review committees. This information is scrutinised or audited as part of a national inspection programme allowing licence authorities to be reviewed, revised or varied as required. Detailed real-time information is not published.

The 1986 Act also requires some retrospective information is collated and presented to the regulator in the form of annual statistical returns itemising licensed animal use: this is published in the form an aggregated annual statistical report (Home Office, 2007). The information supplied does not contain detailed information of the benefits (often the return is supplied before scientific findings are published) or the animal welfare costs. This is a major limitation of the current system and it is in part due to EU reporting requirements which require statistical information be supplied before these additional insights can be captured. Work is ongoing in the UK in an attempt to remedy this without creating a disproportionate increase in compliance costs.

Meantime, by preparing and publishing various thematic reviews as part of an annual report, the Animals (Scientific Procedures) Inspectorate, other

means are used to make some such information available (Home Office (4), 2007).

It is worth comparing this with systems in place in other jurisdictions. Many of the animal welfare insights published elsewhere are in essence providing prospective information representing an average of what is expected to occur in practice: their interpretation requires that it is kept in mind that this information does not purport to be a true description of what range of suffering might be seen or what actually happens in practice. Other schemes provide prospective information based on the worst likely outcome: this does not create a better informed public debate as the welfare costs they imply may never or seldom occur in practice.

In most places real-time information is seldom available other than to those undertaking the animal studies.

Retrospective information is rarely published in detail by users, establishments, funding bodies, journals or others. Even that which is published is often dated and difficult to generalise to other situations.

### **What do the public really want to know?**

There is a genuine and legitimate public interest in decision making – in this context how prospective decisions are taken with respect to whether and on what terms animals should be used for experimental and other scientific purposes. This extends beyond an interest in policies, a general description of the decision making framework, and statistical tables relating to animal use.

It is my belief the public understanding and public debate is best informed by plain-English case-studies.

Whilst there will in some circumstances be individual, local or national interest in prospective or real-time information relating to particular studies or classes of work, detailed information is seldom available to the public. There are a number of reasons for this, but even if these were removed, the original data and records are not written with a lay-reader in mind, and considerable collation, analysis and editorial work would be required to re-present it in context and in a format that would be easily understood by a reasonably well-informed lay person.

For the time being the public's understanding of what is actually happening in practice is possibly best informed by timely and clearly presented retrospective information, and this may be all that is required in instances when the interest is in trends or patterns in animal use.

### **Key concepts**

Before deciding what information requirements should be some crucial questions must be asked and adequately answered:

- who needs the information;
- why is the information required;
- what insights must it provide and what types of inferences must it support;
- what decisions or actions will the information inform;
- when it is required;
- in what format is it required; and
- what are the practicalities and resource implications.

Of equal or greater importance: the limitation of the information to be supplied and uses for which it is not suitable it need to be clearly understood from the outset.

### **The present and the future**

Decision-making, authorisation, definition of technical authorities and compliance checks will always need prospective information, informed by elements of objective professional, expert judgement.

However, insights into what actually happens, and the ability to react in a timely manner will always require real-time information, and in some circumstances retrospective information. Local operational practices and decisions, and assessment of compliance, depend on the availability of objective real-time information.

Policy makers require multiple sources of high-quality, accurate and time information – extending well-beyond any statutory regiments for collection and publication of information.

The public understanding needs all three classes of information – but clearly and objectively presented in a way that is meaningful to lay people.

### **Conclusions**

I would maintain that assessment, regulation and compliance reviews will always and inevitably require highly-detailed technical information requiring objective professional analysis and judgment to extract its true meaning. For example, considerable information and analysis may be required to draw informed conclusions about the scientific merits and relative welfare costs of even seemingly minor protocol amendments or variations.

It is my view that informing the public's understanding and having a better informed public debate of these issues requires information presented in plain-English primarily reflecting the actual outcomes in practice, with enough data to be able to generalise from specific case-studies and to display patterns and trends.

I believe it is difficult (mindful of the current EU reporting requirements) to envision a low-resource single system that is ideally suited to simultaneously satisfying both needs.

At present regulators and local management can effectively mandate what they need for their own purposes. They must nevertheless be receptive and responsive to the need to make sufficient information generally available to maintain public and political confidence in the regulatory system and the welfare costs, necessity and benefits of animal use for these purposes.

*The views expressed in this paper are those of the author, and not necessarily of his employer.*

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