Road Map Resource Pack

FOCUS ON SEVERE SUFFERING

PART 2: PROSPECTIVE REVIEW

2nd edition. March 2016

RSPCA Road Map sheet 1: Lifetime experiences – guidance notes

Below are examples of the kinds of questions you might like to consider with respect to the factors listed in sheet 1. For further information, see also RSPCA Lay Members' Handbook pages 32-33 (refinement).

Sourcing – where will the animal come from? If an external breeder, how do the standards of housing, husbandry and care compare with those at the user establishment? At what age are juvenile animals separated from the dam ('weaning')? How does 'weaning' age compare with good practice guidelines, other facilities, and/or the age at which they would separate in the wild (as appropriate)? If bred in-house, at what age does separation from the dam take place? What measures are in place to ensure that supply meets demand and wastage is minimised? (If there are any surplus animals, what happens to them and why?)

Transport – is this avoided wherever possible, or are journeys refined so as to minimise stress? Are recovery times following transport adequate from both animal welfare and scientific aspects?

Marking for identification – is this minimally invasive and fully refined?

Biopsy for genotyping – is the minimum amount of tissue taken, or could non-invasive techniques be used? Could biopsy be combined with identification (e.g. ear punching in rodents)?

Housing – is a good quality and quantity of space provided, with appropriate group housing (for social animals), environmental enrichment and adaptations for animals affected by procedures (if necessary)?

Husbandry and care – is this sympathetic to the animals' behavioural and sensory adaptations, e.g. are light regimes appropriate for the species, does cage cleaning try to accommodate scent markings and is sufficient recovery allowed before procedures?

Capture, handling and restraint – is it recognised that these can be stressful and are all suitably refined, including minimising episodes of restraint or using positive reinforcement training? The UK NC3Rs has a resource on this topic.

Humane killing – has the least distressing method been chosen, or has the 'default' at the establishment been selected? Could the technique be refined?

It is important to keep up with current good practice in relation to refining all of the above, acknowledging that ranges of experience and knowledge are required to identify, interpret, implement and evaluate refinements. A designated individual such as the Named Information Officer or the AWERB/AWB should be responsible for ensuring that new information on refinement, animal behaviour and biology, and relevant scientific developments is available for review within the facility.

RSPCA September 2015

RSPCA Road Map resource sheet 1 – to complete before the project has started

Predicted lifetime experiences (not including procedures)

Project licence number	
Protocol number	

Factor	Experience of the animal	Welfare issues	Ways of mitigating these
Sourcing			
Transport			
Marking for identification			
Biopsy for genotyping			
Housing, husbandry and care			

Capture, handling and restraint			
Humane killing			

Note: This sheet should be edited and tailored to the species and different factors that may apply under different circumstances. Factors may need to be added, edited or deleted.

RSPCA Road Map resource sheet 1 – to complete before the project has started

Predicted lifetime experiences (not including procedures)

Project licence number	7076/54
Protocol number	1

Factor	Experience of the animal	Welfare issues	Ways of mitigating these
Sourcing	Mice are bred in-house. Supply and demand are carefully matched and animals provided with litter, nest boxes and nesting material. Cages are cleaned weekly.	Distress due to separation of dam and pups at weaning.	Ensure removal from dam is appropriately timed and keep litters together wherever possible. Review frequency of cage change (e.g. fortnightly?) to ensure cage is sufficiently clean but with minimal disturbance.
Transport	Once, between rooms within the same building before procedures begin.	Stress and anxiety due to movement.	Move in home cages, minimise distance, think about timing, ensure sufficient time to recover before any other interventions or procedures.
Marking for identification	Animals are identified using microchips, which involves capture and restraint for insertion.	Distress due to restraint, short term pain of chip insertion.	Trial less aversive capture techniques (see below). Research pros and cons of sedating or anaesthetising mice. Ensure adequate checks in case of longer term discomfort.

Biopsy for genotyping	N/A		
Housing, husbandry and care	Mice are housed in groups of 3 in standard mouse cages with litter, refuges, nesting material and chew blocks. Cages are cleaned weekly.	Space restrictions in standard size caging. Some fighting observed, especially in males, after cage cleaning.	House mice in (empty!) rat cages to provide more space. Trial transferring some litter (not nesting material) from the soiled to the clean cage. Supply males with extra nesting material and remove refuges. Review cage cleaning intervals.
Capture, handling and restraint	Mice are caught and restrained by the tail.	Research indicates that this is distressing and causes anxiety.	Catch mice in cupped hands or tunnel – see NC3Rs resource.
Humane killing	Moved within home cage to chamber where they are exposed to a rising concentration of carbon dioxide.	Stress of being moved to chamber. Distress due to 'air hunger' as concentration increases.	Move to anaesthetising with minimally invasive gaseous agent before switching to CO_2. Research possibility of introducing CO_2 into home cages if housed in IVC.

Note: This example is for guidance only and intended to give an indication of some of the points and factors that could be discussed when conducting this part of the review.

RSPCA Road Map resource sheet 2 – to complete before the project has started

Focus on procedures

Project licence number	
Protocol number	

What does this study involve doing to the animals?	**What will the animals experience? How much suffering might it cause? What might make it worse?**	**How will suffering be reduced to a minimum?**	
	Adverse effects and indicators of these	**Methodology and interventions**	**Humane endpoints**

RSPCA Road Map resource sheet 2 – to complete before the project has started

RSPCA Road Map resource sheet 2 – to complete before the project has started

Focus on procedures

Project licence number	70/6524
Protocol number	2

What does this study involve doing to the animals?	What will the animals experience? How much suffering might it cause? What might make it worse?	How will suffering be reduced to a minimum?	
	Adverse effects and indicators of these	**Methodology and interventions**	**Humane endpoints**
Administration of rheumatoid arthritis inducer	Capture and restraint – distress· Aggression, vocalisation, unwilling to be caught· Administration i·d· or s·c· – pain· Flinching, vocalisation, aggression· Pain or ulceration around injection site· Attention to site, reduction in nest quality, body weight/food	Competent, empathetic capture (e·g· not by tail) and handling, habituate to handling and restraint· Use gaseous anaesthesia for i·d·; inject into rump, not tail base (if tail base is painful, restraint by the tail will hurt)· Minimise volumes and doses, use multiple sites if large volumes· Ensure injectate formulated to minimise adverse effects Inject into rump (less risk of ulceration); never inject into the foot; if attention paid to site	Humane endpoints with respect to administration of inducer in general: - Ulceration that is painful, shows no signs of healing or becomes infected· - If an ulcer reaches >5 mm, the vet or senior animal technologist should be informed and consulted about treatment· Animal should be humanely killed if no signs of healing within 3 days·

	intake reduction, reduced grooming, reduced social interaction, physical appearance of ulcers· Adverse effects due to adjuvant, e·g· granuloma, lesions· Indicators as for pain/ulceration above·	apply topical anaesthesia and review injection protocol; choose needle gauge with care· Ensure that least harmful adjuvant possible has been used; review literature and avoid FCA (e·g· trial incomplete Freund's)	
Allowing arthritis to develop	Painful joints, sore feet, lameness, disability – pain and distress· Altered gait, swollen paws, favouring paws, reduced grooming, discoloured skin· Acute pain· Flinching, vocalisation, attention to painful site·	Implement husbandry refinements e·g· long drinking nozzles; pick up and handle using washed Vetbed; give analgesia if possible, e·g· opioid during 'attack' phase, provide appropriate enrichment to 'shift' attention·	Prolonged failure to weight bear on a limb· Spontaneous vocalisation when picked up or handled· 20 % weight loss, or 15 % if this does not begin to reverse within 5 days· Severe paw swelling, using a numerical index or paw volume·
Other issues	Inherent severe arthritis in some models or strains	Explore potential to answer the same question using a less severe model or less susceptible strain·	

Note: This example is intended to give an indication of some of the points and factors that could be discussed when conducting this part of the review. It is for guidance only and is not intended to be exhaustive for this type of procedure. It is based on the RSPCA report on Applying refinement to the use of mice and rats in rheumatoid arthritis research, *Inflammopharmacol* DOI 10.1007/s10787-015-0241-4 which is open access here: http://link.springer.com/article/10.1007/s10787-015-0241-4

Slide 1 Road Map resource pack: : Part 2; Prospective review

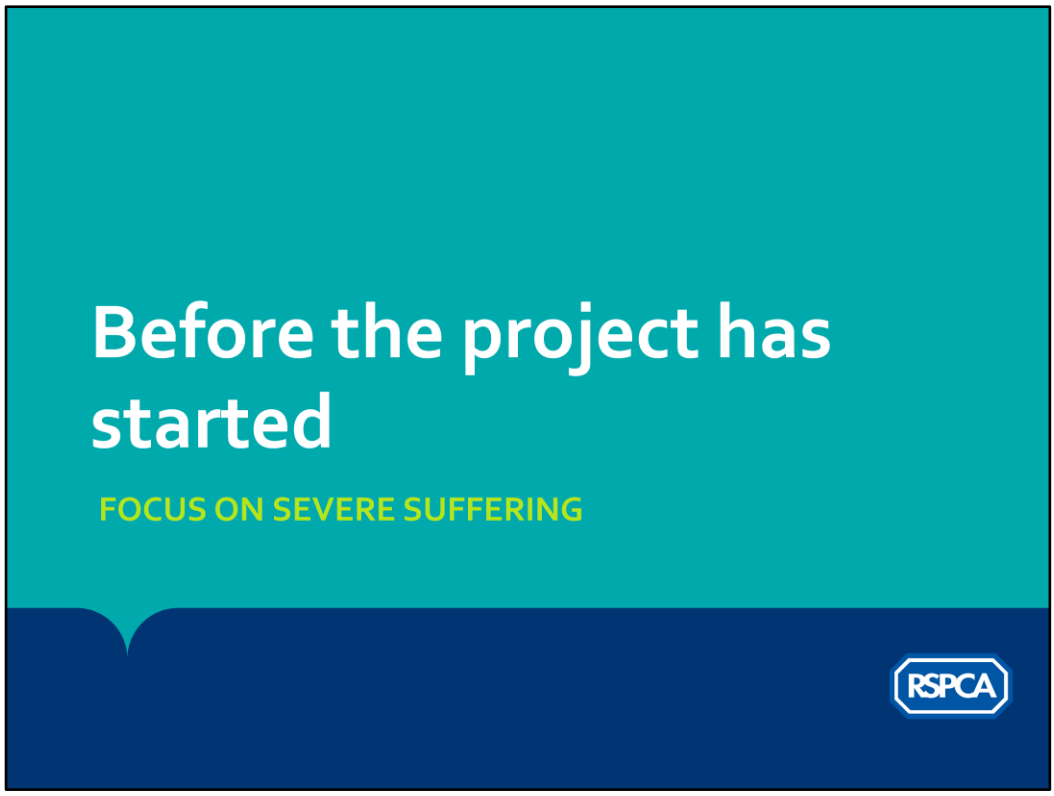
This set of slides was prepared by the Research Animals Department of the RSPCA, and is intended primarily as a practical guide for Animal Welfare and Ethical Review Bodies (AWERBs) or other institutional animal care and use committees, to establish a mechanism towards reducing and avoiding severe suffering within their establishments.

The resource is intended to be accessible to all members, each of whom may have sat on the AWERB or committee for some time, or may be relatively new to their role. Some members may thus be very familiar with the information and approaches set out in these slides, whereas the materials, technical details and processes mentioned will be less well known to others.

Each slide has associated notes which provide a guide to the points you can make while giving the presentation, but the intention is for you to use your own script rather than read the notes as they are.

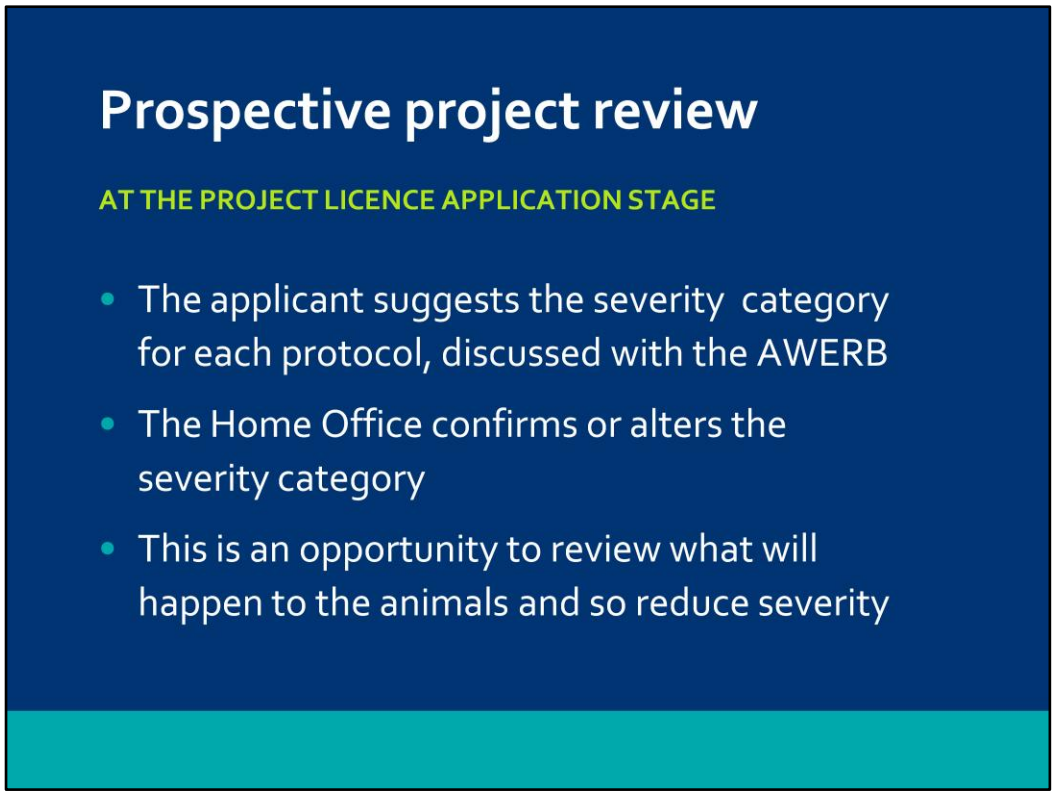
Please read the Guidance for Facilitators before giving this presentation.

You can contact the Research Animals Department if you would like to receive an editable version of this resource or any additional information: research.animals@rspca.org.uk



Slide 2.1 Reviewing procedures that have the potential to cause severe suffering

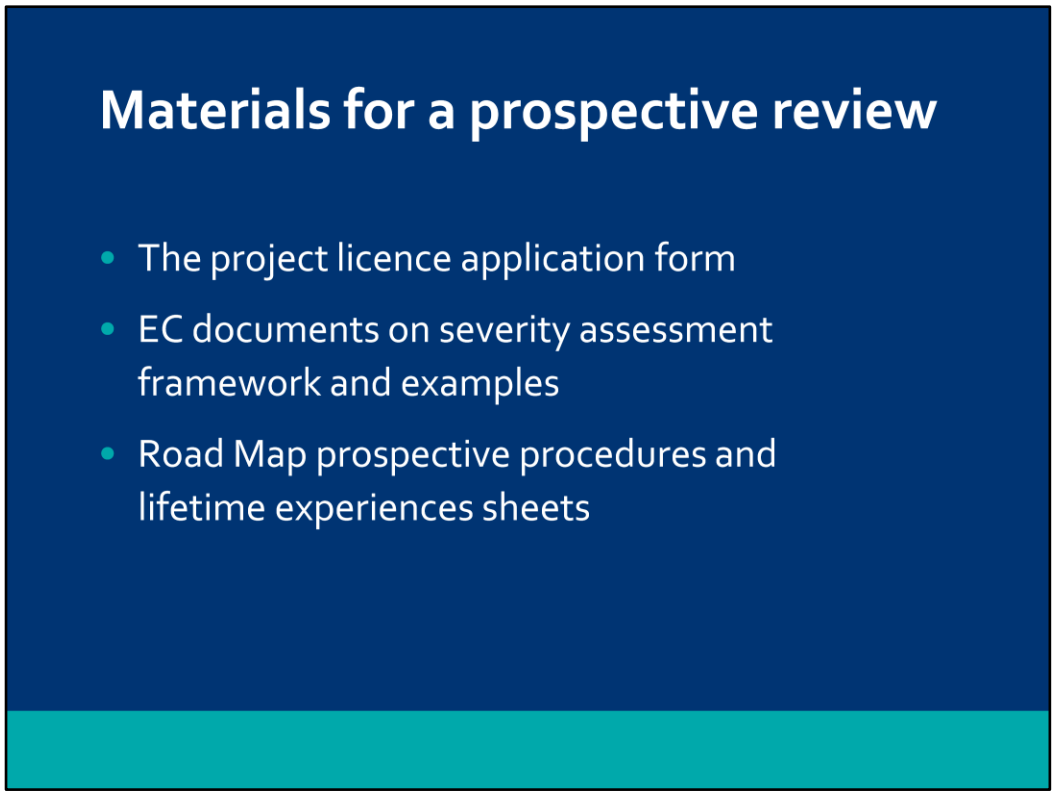
This series of slides aims to guide the AWERB (or other review body) through a review of potentially severe procedures, to see whether severity can be reduced.



Slide 2.2 Reviewing and reducing severity at the project licence application stage

Directive 2010/63/EU requires all procedures to be prospectively classified according to the expected level of severity. The categories are unclassified, mild , moderate and severe (details and definitions can be found here: http://ec.europa.eu/environment/chemicals/lab_animals/pdf/Endorsed_Severity_Assessment.pdf).

The project licence applicant suggests the severity category for each protocol, based on the highest severity anticipated for any animal in the study, and this should be discussed with the AWERB, which may challenge this if it believes it to be inappropriate. The Home Office Animals in Science Regulation Unit (ASRU) will then confirm or alter this. However, before the application goes to ASRU, the AWERB should have the opportunity to review what will happen to the animals and identify ways to reduce severity.



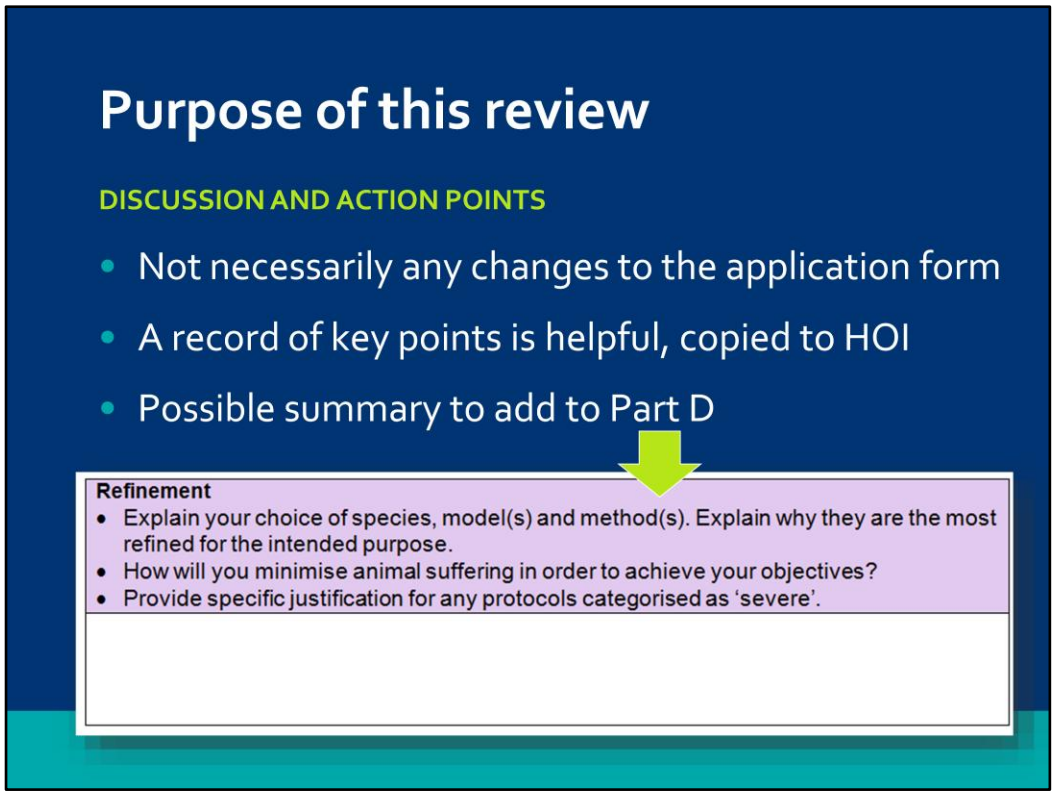
Slide 2.3 Checking the materials required for prospective review

We are now going to review the project in question, to see whether and how severity can be reduced – ideally from severe to moderate or even less, but any reduction in severity will be a positive step.

We will use

•The project licence application form
•The European Commission document on severity assessment framework and its accompanying document, which sets out worked examples
•The Road Map prospective procedures and lifetime experiences sheets, with guidance notes

[Before beginning the review, it would be helpful if members of the group read:
•section 5 of the RSPCA/LASA Guiding Principles, which addresses project review, and
•chapter 4 of the RSPCA Lay Members' Handbook, which addresses reviewing project applications.]



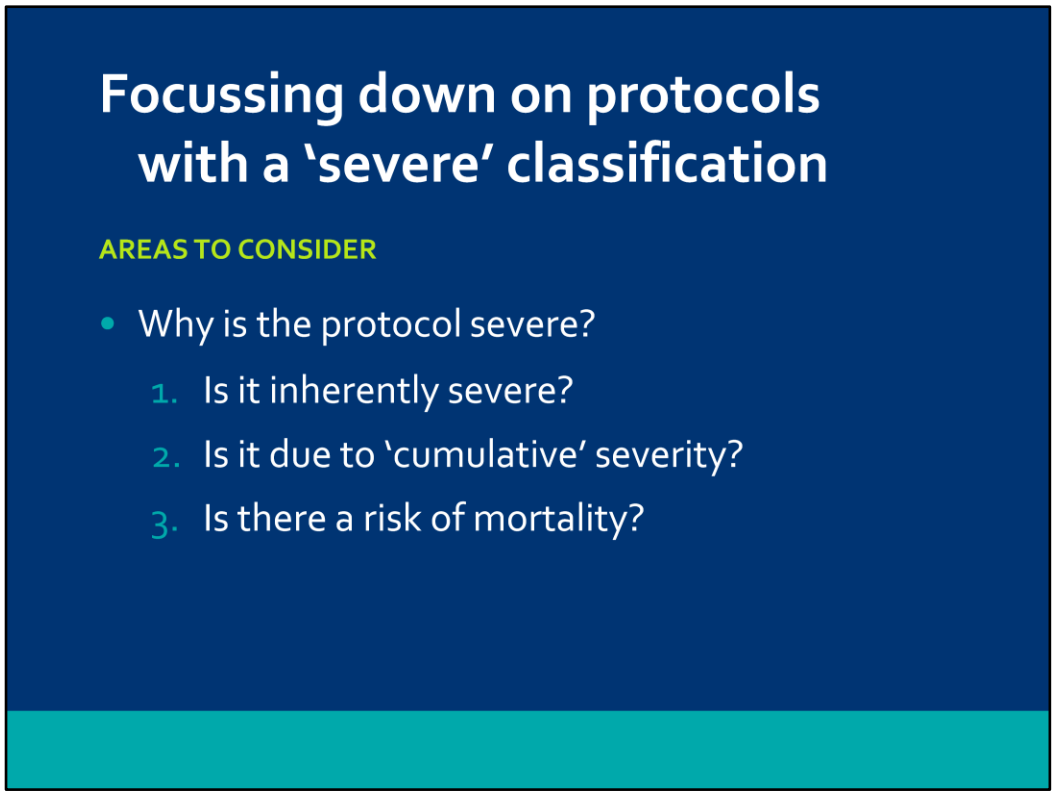
Slide 2.4 The purpose of the prospective review

The objective of this review is to focus on procedures that have the potential to cause severe suffering, identify factors that contribute towards causing this level of severity and explore the possibility to avoid or refine these.

This need not necessarily result in editorial changes to the protocols as described in the draft application form.

The most important aim is to ensure that individuals with a range of knowledge, experience, expertise and approaches are able to have an in-depth and focused discussion about the animal's experience and how this can be refined.

Potential outcomes could be a record of the key points identified during the discussion, with actions for specific individuals, which could be copied to both the AWERB and the Home Office Inspector, to demonstrate how the review was done. It may also be appropriate to add a brief summary of the main action points to Part D of the licence application.



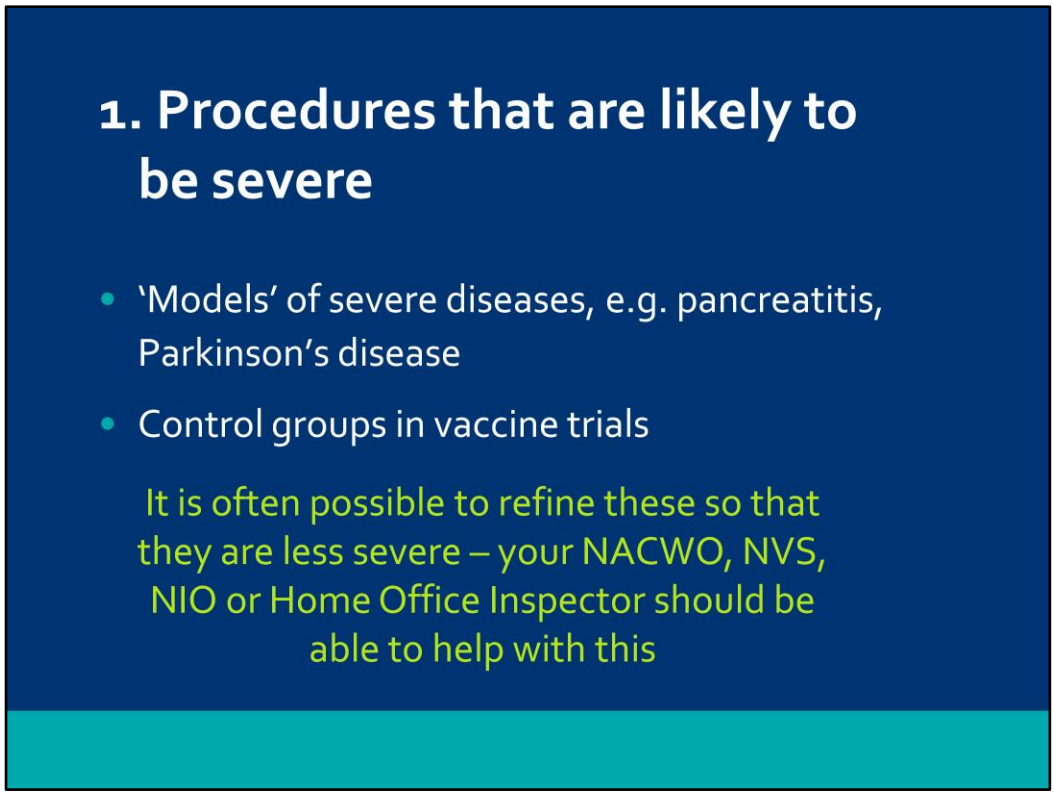
Slide 2.5 Factors that may cause a protocol to be 'severe'

There are many factors that may combine to increase the risk that a protocol will cause severe suffering, but we can divide them into three main areas.

1. Some protocols are inherently severe in themselves;
2. some may include a number of steps that are not severe in isolation, but combine to cause severe suffering; so-called 'cumulative severity'; or
3. there may be a risk of mortality.

If animals are 'found dead', severity is assumed to be severe unless there is evidence otherwise.

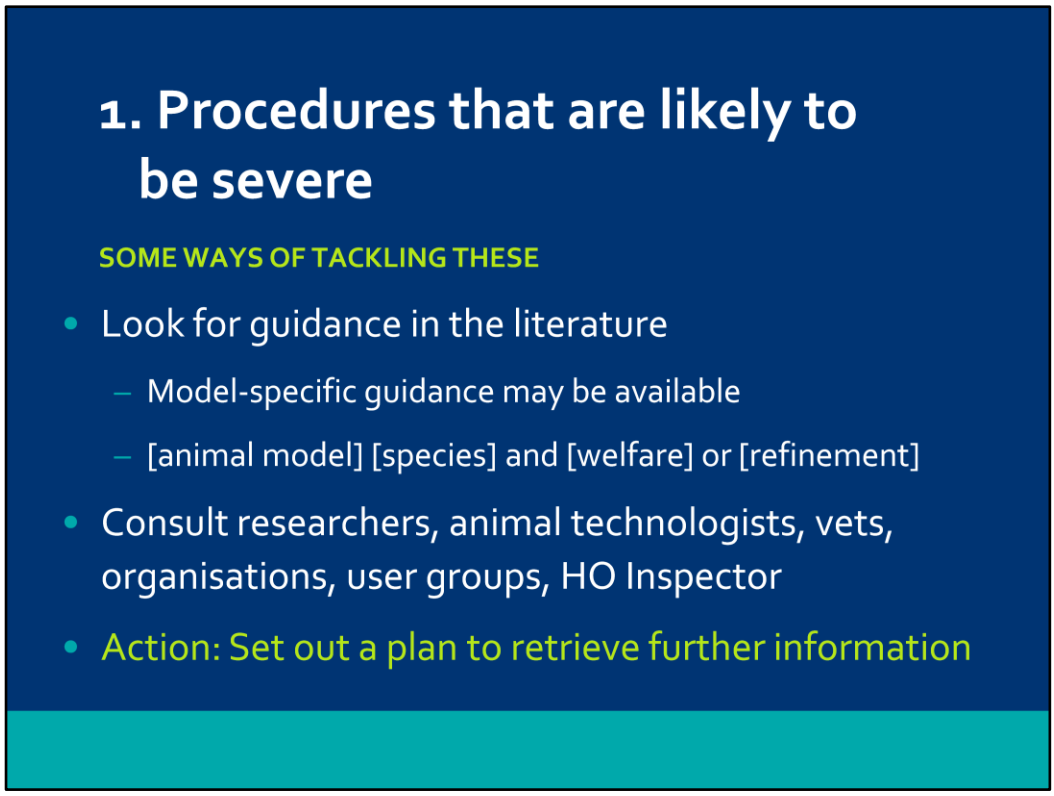
We will consider each of these areas in turn, with particular emphasis on the second one.



Slide 2.6 Procedures that are likely to be severe

Some procedures are more likely to be severe than others, for example some 'models' of diseases or conditions that cause high levels of suffering in human or veterinary clinical cases, or that require severe procedures to *create* a model (even if animals do not subsequently experience severe adverse effects in the longer term). Control groups in some vaccine studies, i.e. those exposed to the disease without receiving the vaccination, may also experience severe suffering, depending on the disease.

It is often possible to refine models and protocols like these, and your Named Persons and regulator should be able to help.



Slide 2.7 Approaches to tackling inherently severe procedures

There are several ways in which it may be possible to refine 'inherently severe' procedures.

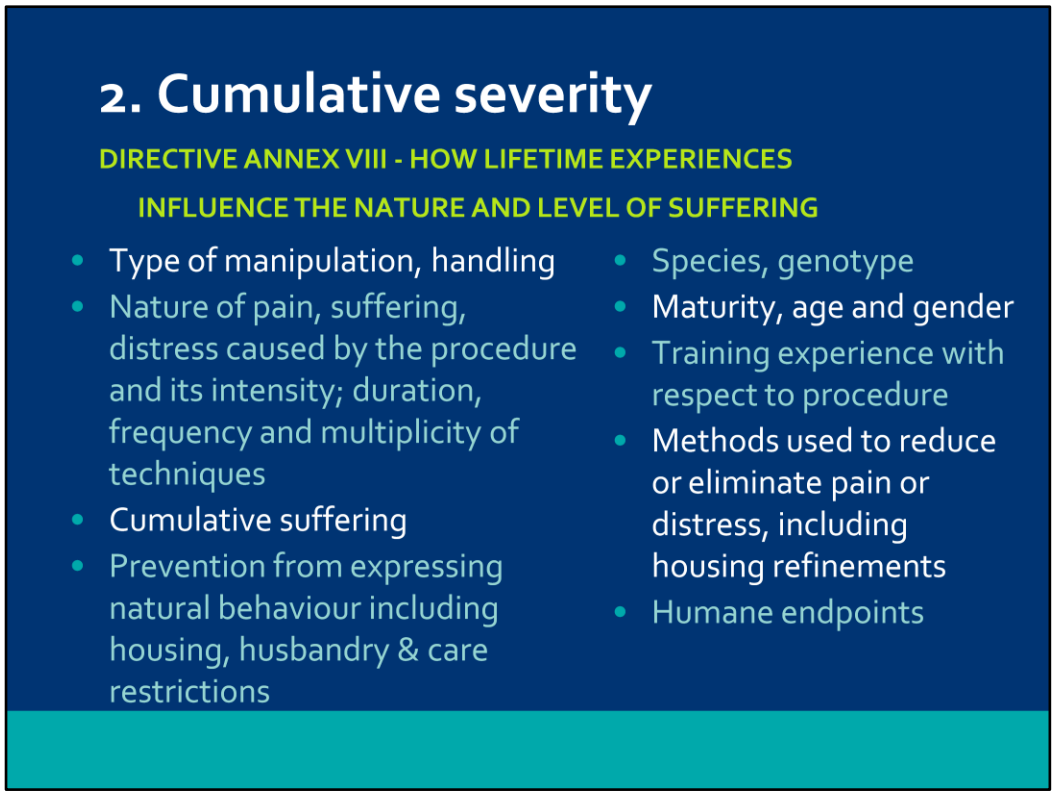
First, you can search the literature for guidance on refining the specific procedure in question. For example, RSPCA-convened expert working groups have produced guidance on refinement of severe procedures and to date reports are available for seizures, convulsions and epilepsy, experimental allergic encephalopathy, sepsis and rheumatoid arthritis.

An internet search on [animal model], [species] and [welfare] or [refinement] can be a useful starting point to find reports like these.

It is also a good idea to consult other researchers, animal technologists and veterinarians with experience in the field, the Home Office Inspector, and relevant societies, organisations and user groups. As well as any contacts that direct colleagues may have, there are online discussion fora such as COMPMED, LAREF and VOLE. These all require membership in order to assess current and archived discussions, but researchers, Named Persons and vets should be able to access these.

Action: While everyone is sitting around the table, this is a good opportunity to draw up a plan to retrieve further information about the potential to refine the protocol in question, tasking individuals with (i) literature searches, (ii) consulting internal and external colleagues including the Inspector and (iii) posting questions on online discussion fora – with deadlines. The outcome could be discussed either by email or meeting in person, depending on whether there are implications for significant changes to the protocol.

Regardless of whether work has already been done to focus on the procedure and refine it, an essential step is to review the animal's lifetime experiences and identify refinements for as many potentially distressing or painful events as possible.



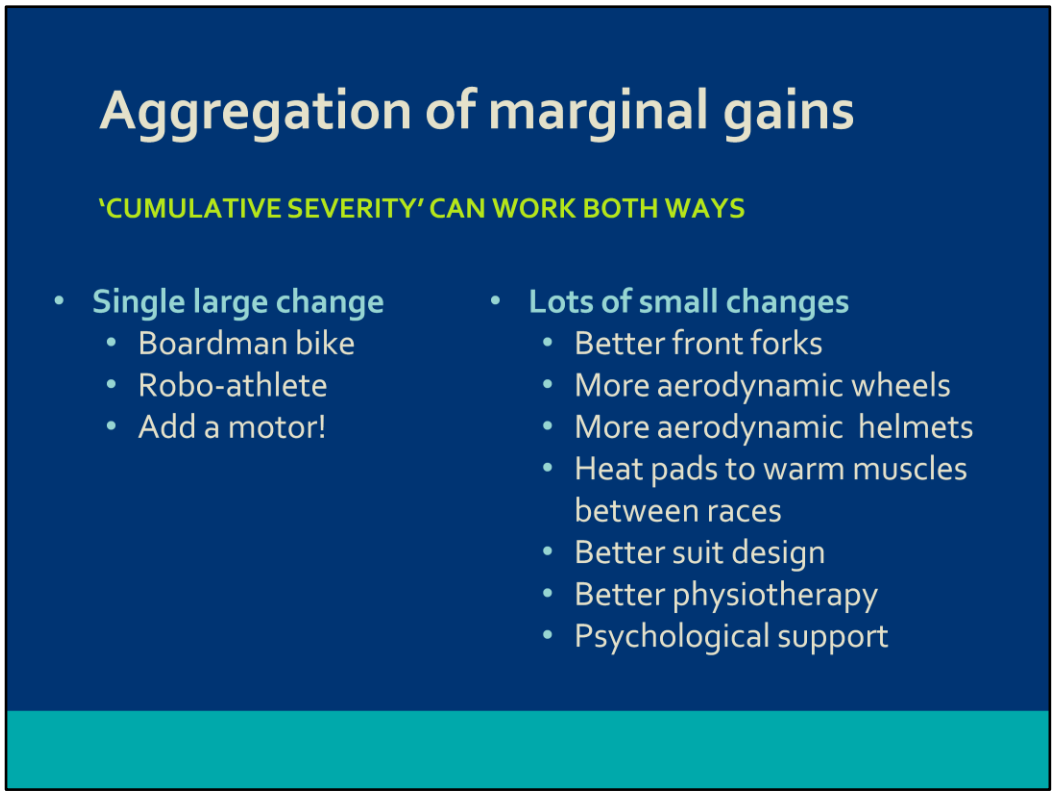
Slide 2.8 Cumulative severity

Annex VIII of Directive 2010/63/EU, which addresses prospective severity classification, explains that 'cumulative suffering within a procedure' is a factor that should be taken into account when assigning the severity category. Other factors listed in the Annex include handling, duration and frequency of techniques, restrictions on housing and care, training experience of the animal, any refinements that have been implemented and humane killing methods.

This sets out how animals used in research and testing can experience a number of potentially painful or distressing events (harms). These include transport, marking for identification, capture, handling, restraint, laboratory housing and husbandry, scientific procedures and the after effects of these, and humane killing.

It is well recognised that repeated stressors like these can affect overall severity, but it is not always easy to predict exactly how their effects interact and impact upon one another. So while the term 'cumulative' severity is often used, harms do not 'accumulate', or simply add up. Animals may become sensitised to certain procedures, so suffering is increased, or they may habituate (become used) to them, which can reduce suffering. Allowing sufficient recovery time following stressful events such as transport or cage change before conducting a procedure can reduce cumulative effects, although the impact of some procedures (e.g. surgery without the most effective perioperative analgesia regime) may be long-lasting or permanent.

Two essentials for understanding, assessing and reducing cumulative severity are (i) thorough review of the animal's lifetime experiences, identifying every source of potential suffering and implementing refinement for each one, and (ii) an effective welfare assessment system.



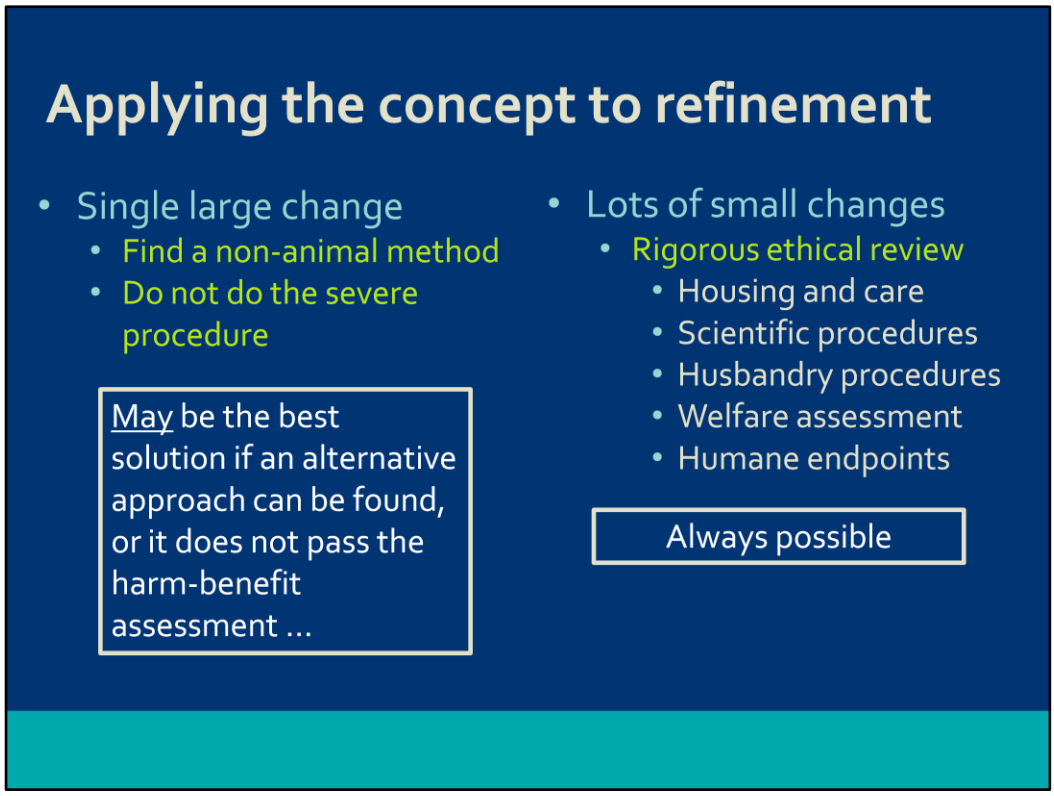
Slide 2.9 The concept of the 'aggregation of marginal gains'

A useful concept to apply when reviewing the animal's lifetime experience is the 'aggregation of marginal gains'. While a number of potentially painful or stressful events can combine to increase severity, conversely, applying a number of smaller refinements can lead to a significant reduction in overall suffering.

A good analogy for this was the success of British cycling under the leadership of Sir Dave Brailsford, using the approach of achieving an aggregation of marginal gains. If you want to be the best, you could invest your time in looking for the next big paradigm shift in technology (such as the Boardman bike), to overtake the rest of the field in a single step.

Alternatively, you could break down all the component parts that contribute to a successful cycling performance, and make each one just a little bit better in a systematic, iterative way; e.g. slight changes to front fork, helmet, and suit design, and improvements to dietary, physiotherapy and psychological support to riders. Combining small improvements like these can lead to a significant improvement in performance for the elite, with the added benefit of raised standards for all of the team.

This concept is essentially the opposite to cumulative severity, in which a number of small improvements combine to make something significantly less severe for the animal. It is applied to refinement by systematically breaking down the lifetime experience of the animals into component steps, identifying the potential for physical or psychological suffering, and putting in place measures to eliminate or ameliorate this suffering.



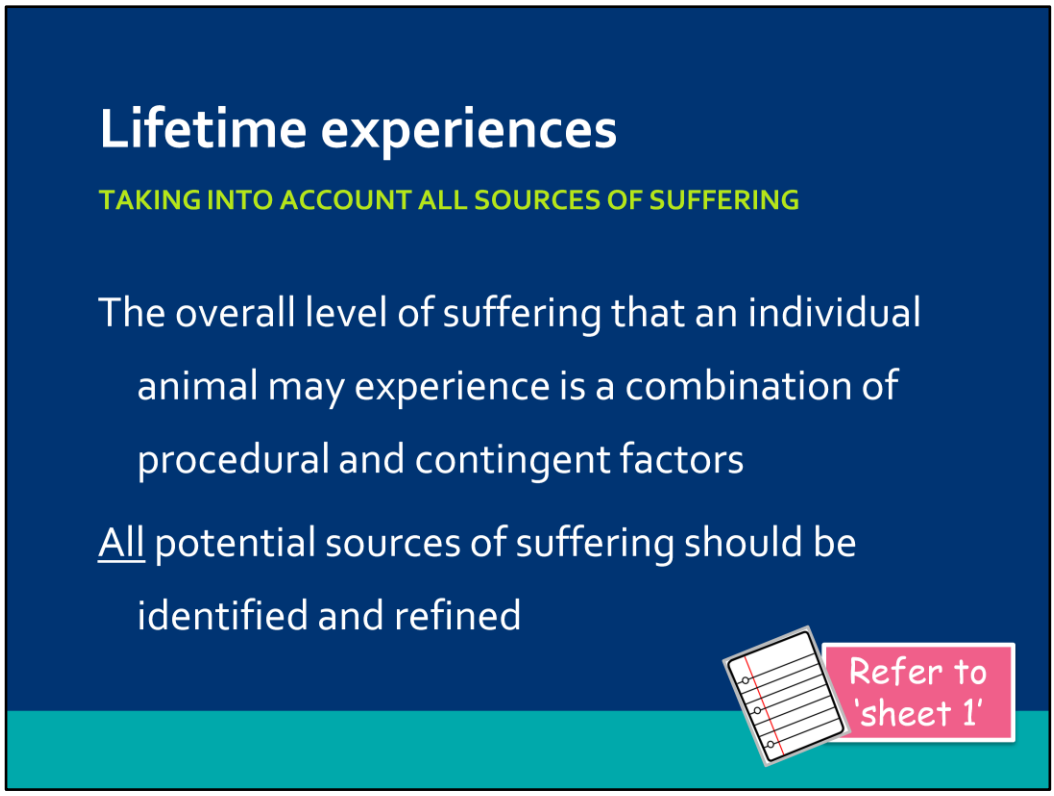
Slide 2.10 Applying the concept of marginal gains applies to refinement

This is how the concept of aggregation of marginal gains applies to refinement.

Looking at the left side of the slide: on the one hand, simply not doing the procedure may be the best solution if there is an alternative approach that will obtain equivalent information , or if the decision is made by the researcher, AWERB or regulator that the likely harms cannot be justified by the potential benefits.

Looking at the right; on the other hand, if neither of these apply then it is always possible to review the animals' lifetime experience and make a number of small improvements that can combine to result in significant reductions in severity.

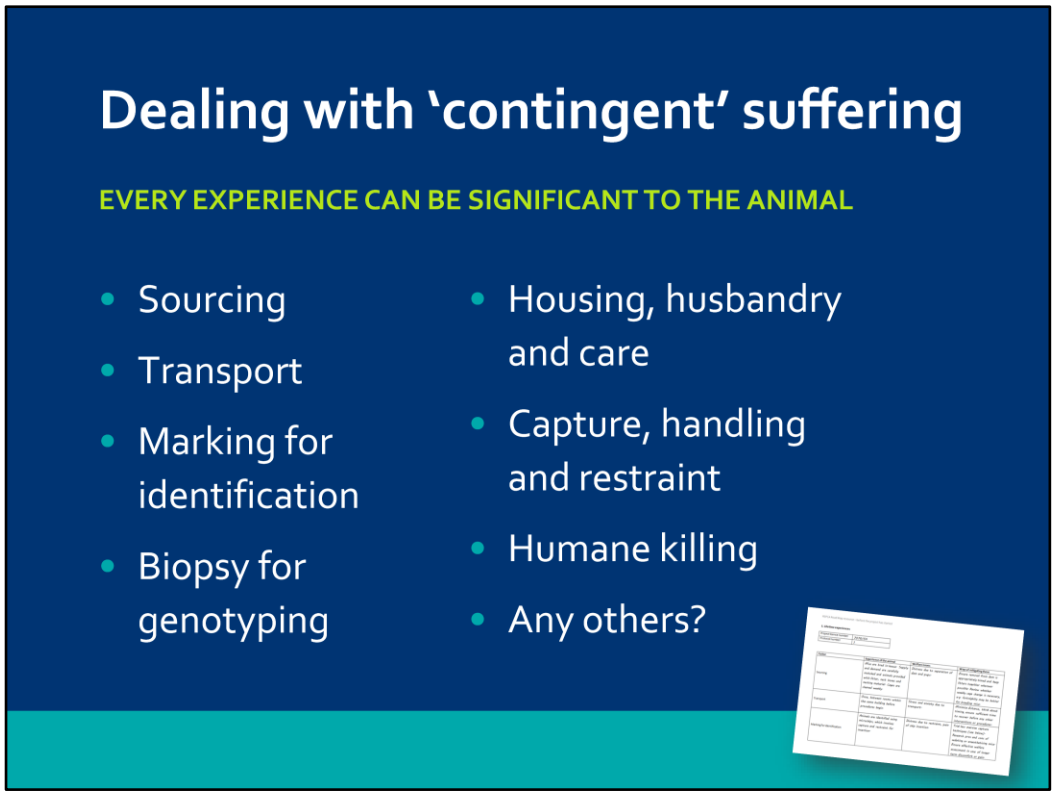
[For a short article explaining the concept further, see http://pilas.org.uk/refinement-lessons-from-the-2012-olympics/]



Slide 2.11 Reviewing the animal's lifetime experiences

[This requires: sheet 1: Lifetime experiences, its accompanying guidance notes and the example sheet.]

A review of the lifetime experience needs to take all potential sources of suffering into account. This review looks at both procedural factors, which are adverse effects directly caused by the procedure and its after effects, and contingent factors, which are not directly due to procedures but are nevertheless included when reviewing cumulative severity, because these can have a significant impact on welfare.

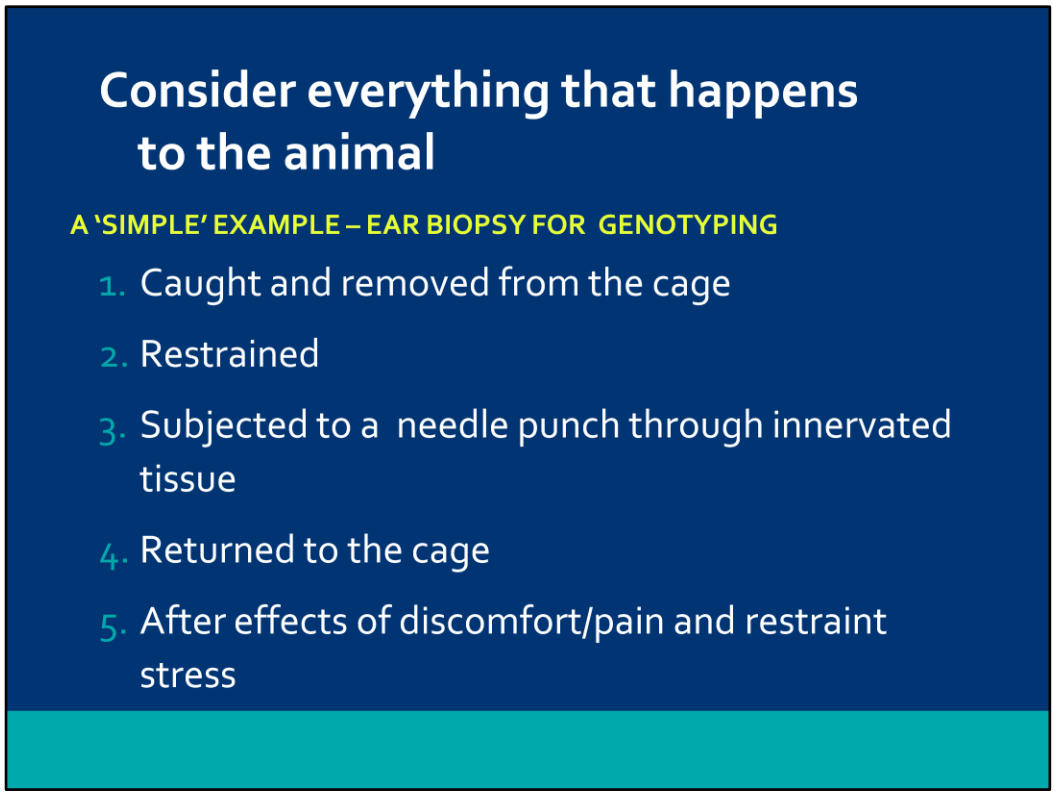


Slide 2.12 Identifying causes of contingent suffering

First we will address contingent factors using sheet 1, 'Lifetime Experiences', and its guidance notes. Not all of the factors listed in the first column will be applicable, but for those that do apply, please discuss and try to predict what the animal will experience, what the welfare issues might be and how these could be mitigated. The guidance notes and example sheet aim to help identify significant experiences for the animals. Many of these will already have been addressed in establishments that follow good practice, but it is always a useful exercise to review them regularly to see whether any new information about animal behaviour, welfare or refinement has come to light.

[Useful materials: Pages 32-33 of the RSPCA Lay Members' Handbook lists issues to be considered under 'refinement'.]

[Please allow time for, and facilitate, discussion on the entries in the sheet. Input from Named Persons should be especially valuable here. Following discussion, an action plan should be drawn up if there are any tasks that arise as an outcome of the discussion; for example, looking into new sources of animals or trialling different group sizes.]

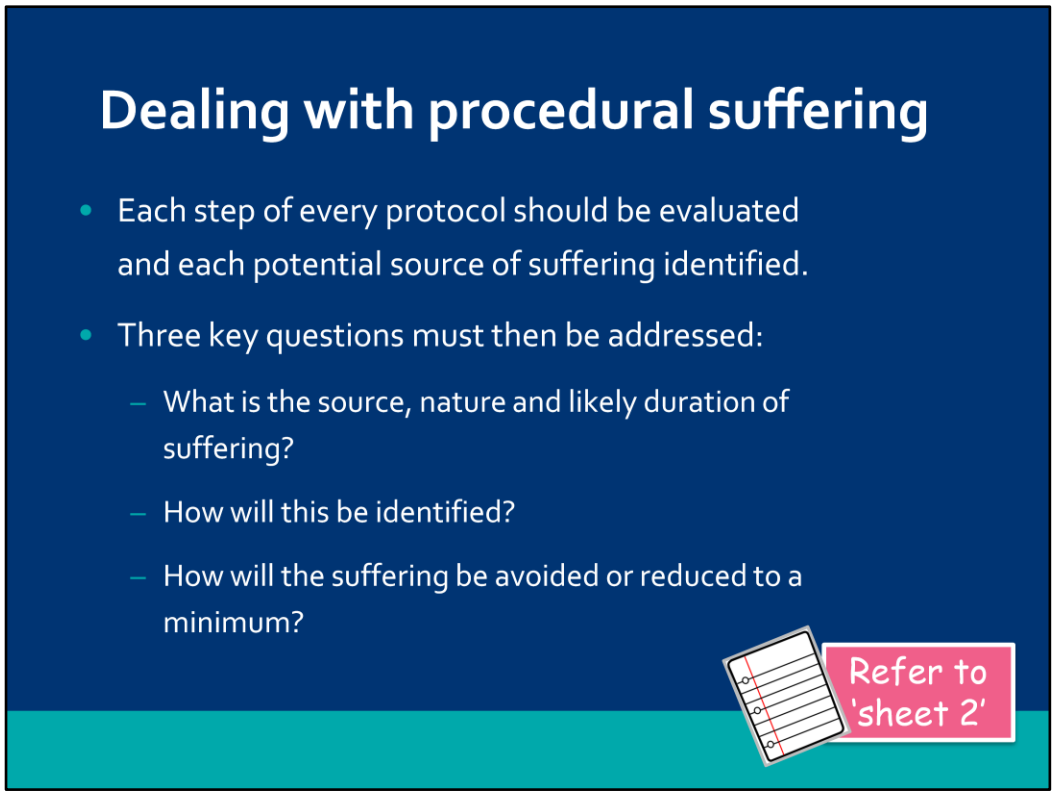


Slide 2.13 An example to help facilitate filling in the sheet

Although we can never know exactly what an animal is experiencing (any more than we can reliably know what another human actually experiences), we can use knowledge about animal biology, behaviour and welfare to predict what an animal is likely to find painful, distressing or anxiety-inducing.

Taking an apparently simple procedure such as ear biopsy for genotyping in a mouse as an example; this may appear to be of little consequence from the human point of view, but from the animal's perspective it is likely to be more significant. It involves capture and restraint, which are potentially distressing (especially if the mouse is caught by the tail as opposed to in cupped hands or a tunnel). A needle punch through the ear will be painful, and even if the acute pain is transient there may be longer lasting effects of discomfort or pain and distress, from which the mouse would need time to recover.

Although ear punching is likely to be preferable to tail tipping for biopsy, especially if combined with identification, the point to remember is the need to think of the animal's experience step by step, giving them the benefit of the doubt and identifying ways to reduce suffering. In the case of ear biopsy, this could include refining capture, ensuring punches are sharp and of minimum diameter, using aseptic technique, providing a refuge to retreat to post-procedure and ensuring that staff are trained, competent and empathetic with respect to all aspects of the procedure.



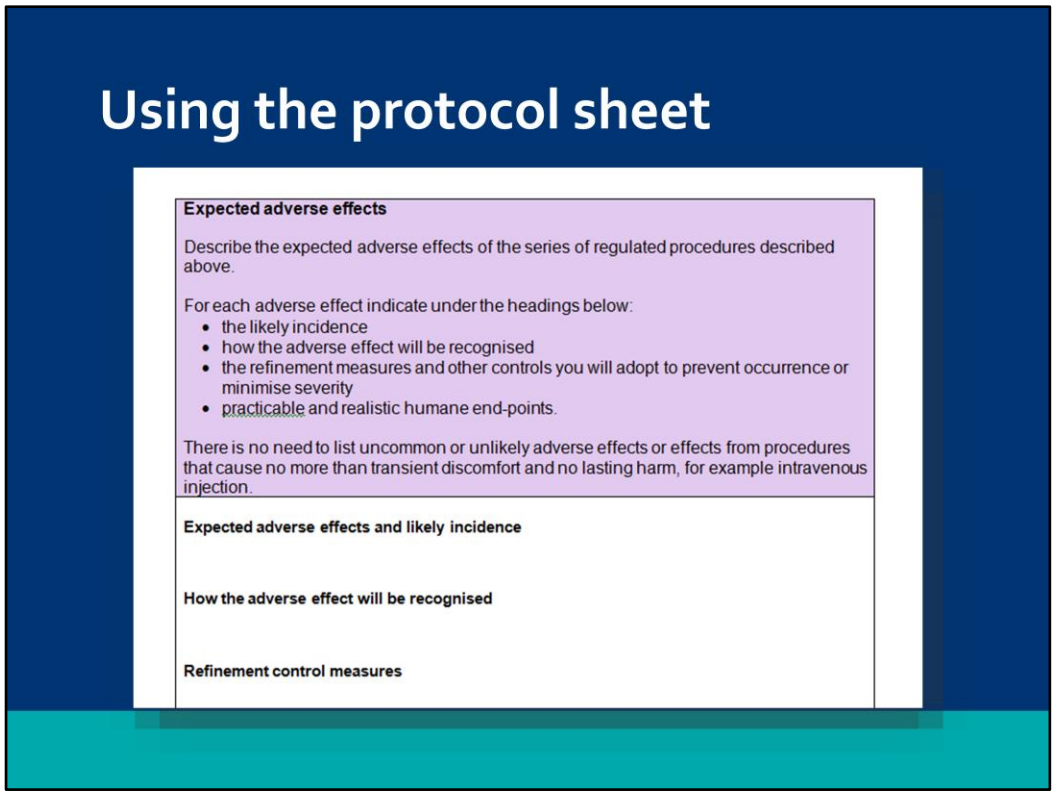
Slide 2.14 Reviewing the protocol sheet

[This requires: the project licence application and sheet 2: Focus on procedures, with examples.]

The next step in the review is to look at the protocol sheet, with the aim of reflecting on what will be done to the animal, identifying what the animal will experience, how they may suffer, how pain or distress will be identified and how suffering will be minimised.

Key resources to guide this process are:
•The European Commission document on severity assessment framework and its accompanying document, which sets out worked examples
•The Joint Working Group on Refinement report on welfare assessment

Useful further information can be found in:
•Section 5 of the RSPCA/LASA Guiding Principles, which addresses project review, and
•Chapter 4 of the RSPCA Lay Members' Handbook, which addresses reviewing project applications.

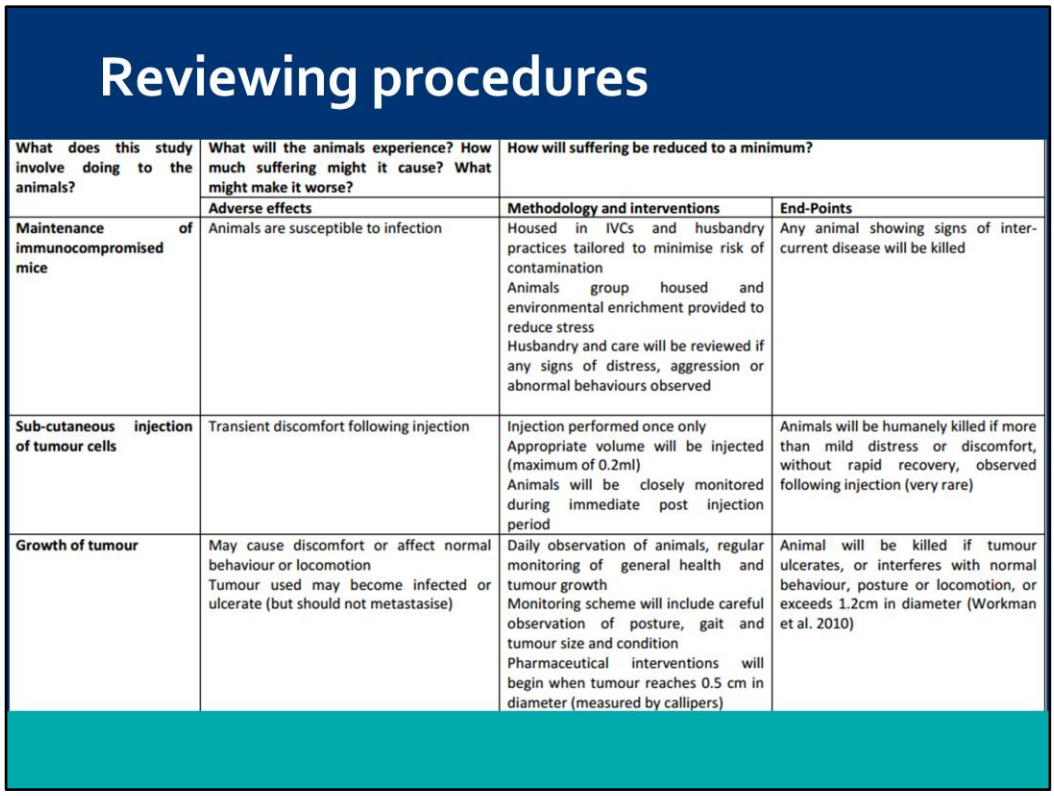


Slide 2.15 The protocol sheet within the project licence application

Under 'Expected adverse effects', the applicant should have listed

•Expected adverse effects and likely incidence
•How the adverse effect will be recognised
•Refinement control measures
•Humane end-points and limits of severity

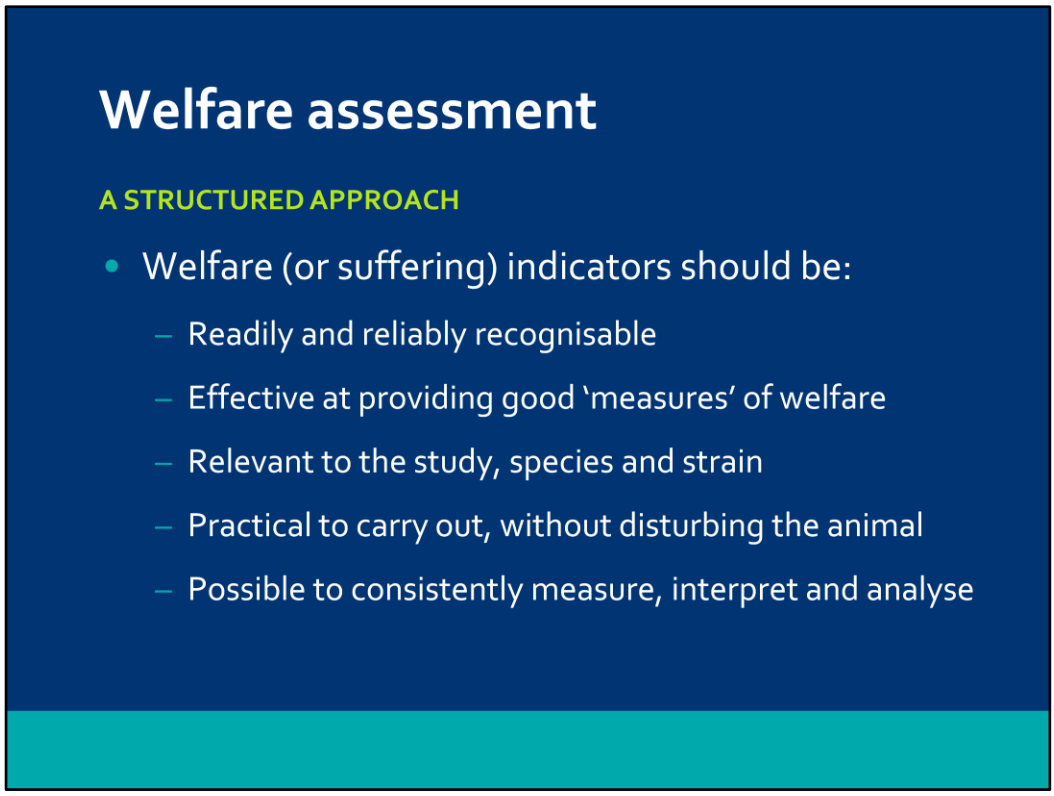
These should provide information that will help to fill out sheet 2, and/or identify further areas for discussion between the applicant, Named Persons and other AWERB members.



Slide 2.16 The basis for sheet 2

Sheet 2 has been taken directly from the European Commission examples for Member States to illustrate the process of severity classification – the only edit has been adding 'indicators of adverse effects' to column 2. Using this sheet to review severity will therefore help to ensure that all steps have been taken to minimise suffering, as required by the Directive and ASPA.

The aim is to carefully consider every entry in the project licence protocol sheet, using the information provided by the applicant as well as the experience and questions of the other AWERB members, to ensure a full and comprehensive review. There are some good examples in the EC document, like this one here, and there is also a worked example supplied with sheet 2.



Slide 2.17 Using the Road Map process to help set out a structured welfare assessment

Considering every step of the protocol, focussing on how each might be further refined and what the most relevant indicators of suffering might be, should help to set out an effective welfare assessment system that accords with the European Commission's requirements, which are listed on this slide.

Slide 2.18 Using the EC guidance to help set out an assessment protocol

There may or may not already be a welfare assessment system in place for monitoring the animals on the study.

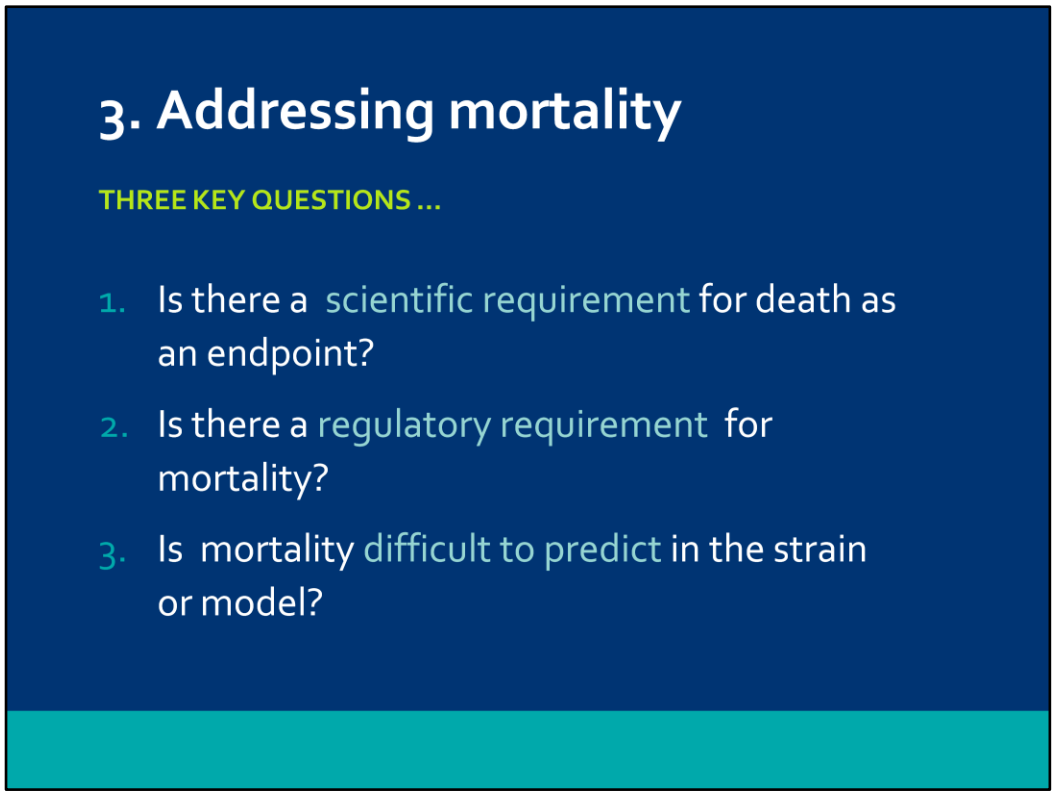
The filled-in sheet 2 can now be used to either help set out a welfare assessment, recording and monitoring system, or to refine the current approach, using the EC guidance as a template. Page 13 onwards of the 2012 document on a severity assessment framework begins by dividing potential indicators into 6 high level categories, listed on this slide, which are then subdivided into 'areas to focus on' and 'specific indicators to monitor'.

Sheet 2 can be used to identify indicators to monitor, and the EC document can guide this process and also help to ensure that there is an appropriate range of different indicators and that important high level categories are not omitted.

The refined welfare assessment protocol will be critically important in detecting and reducing suffering throughout the procedure, and will be used in the ongoing/midterm project reviews and the actual severity assessment.

Action: Sheet 2 should now be used to refine the welfare assessment protocol, either at the time of review or subsequently by a different group, e.g. the welfare assessment 'team' (see JWGR report).

Resources:
•The European Commission document on a severity assessment framework and its accompanying document, which sets out worked examples
•The JWGR report on welfare assessment



Slide 2.19 When suffering is severe because of the potential for death

We will now move on to the third potential cause of severe suffering; mortality.

Directive 2010/63 states that death as an endpoint should be avoided wherever possible and that humane endpoints should be used instead. During the project evaluation process, any potential or requirement for death must be clearly identified and steps implemented to avoid this or evidence produced to justify it.

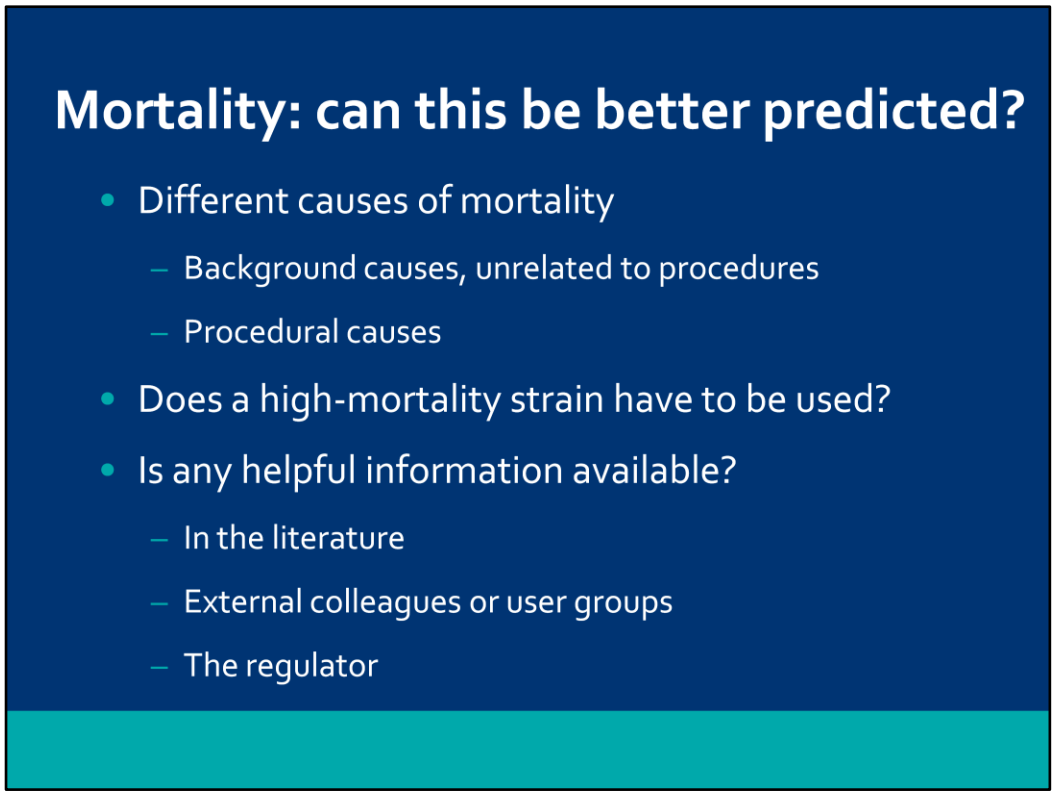
If there is a proposed scientific justification for death as an endpoint, the applicant should be able to explain and defend this to the AWERB. One approach could be to ask the applicant what they would do if they were simply told 'no' and had to implement humane endpoints instead. Would this have a negative effect on translatability? Could the experimental approach or design be altered to avoid mortality and still yield useful information? Could a pilot study be conducted to evaluate these questions?

Action: If the applicant proposes that there is scientific justification for death as an endpoint, ask them to explain this to the AWERB and include a discussion of the questions above. The web page on 'compatibility with science', and its examples, should be useful:
http://science.rspca.org.uk/sciencegroup/researchanimals/severesuffering/scientist/science

Any perceived or actual regulatory requirements for death as an endpoint should be rigorously examined and critically challenged. For example, the OECD recognises that 'with increasing knowledge and experience, investigators in animal research will be able to identify more specific, early humane endpoints in the form of clinical signs for impending death or severe pain and distress. This would permit international harmonisation of these humane endpoints.' Researchers and establishments should challenge regulatory bodies to accept evidence that death can be predicted and accept data obtained from tests in which humane endpoints have been defined and implemented.

Action: If it is believed that there is a regulatory requirement for death as an endpoint, task an individual or small group with researching this, to see how flexible the requirements are in practice and whether there is actually scope to implement humane endpoints.

Mortality can be genuinely difficult to predict in some cases. For the purposes of actual severity reporting, the death of an animal must be reported as severe suffering unless an 'informed decision' can be made that severe suffering did not occur.



Slide 2.20 Better ways of predicting mortality

Some mortality is genuinely unpredictable or difficult to avoid – but knowledge and approaches to detecting relevant indicators are developing and there may be ways of reducing deaths or avoiding death completely.

Some strains have an inherent level of background mortality that can be hard to avoid. For example a 0.5 % incidence may appear to be low, but this could result in 5 deaths in every 1,000 animals. If relevant, the AWERB could discuss what level of background mortality is 'acceptable', according to local values – and question the necessity and/or justification for using strains with a mortality rate above this. Would it be possible to answer the question using another strain?

Action: If the mortality is due to procedures and is difficult to predict, the AWERB could task an appropriate member (e.g. the researcher or a NACWO or NIO) to research and consult as to whether there is any new information on ways of predicting mortality within the protocol. For example, telemetered body temperature using microchips has greatly improved the ability to predict death in a number of fields, such as vaccine testing.

Slide 2.21 Review of the session

At the end of the session, you may have covered some or all of these areas, depending on the nature and purpose of the procedure (read through these).

Action: It is important to ensure that someone is responsible for drafting agreed outputs, such as producing reports for specific individuals and for the AWERB, plus to implement any edits that have been agreed to protocol sheets or summaries for Part D of the application form. It is also helpful at this stage to plan any necessary follow-up meetings, for example to review information retrieved and see whether any measures can be trialled or implemented as a result, or once the project has begun to evaluate the success of potential refinement measures and welfare assessment protocols.

End of the session