Roadmap to reducing 'severe' suffering

Aim of this resource

To enable the AWERB to help reduce, and avoid, severe suffering at the establishment; and to effectively advise on refining procedures at all severity levels.

Relevant AWERB task

Advising staff on animal welfare and the application of the 3Rs; promoting a Culture of Care; establishing and reviewing operational processes for monitoring, reporting and follow-up in relation to animal welfare.

Recommendation

Initiate a review, using the 'Roadmap' approach set out in this sheet, of protocols which currently, or could, involve 'severe' suffering. Use the Roadmap to review cumulative effects, and identify refinements, at all severity levels.

The issue

Many individuals and establishments are making dedicated efforts to reduce the harms experienced by animals, as required by the ASPA. There are also ethical, animal welfare and scientific benefits of reducing, or ideally, avoiding 'severe' suffering. Although the number of experimental procedures with severe actual severity is falling year on year, a significant number of procedures still cause severe suffering - almost 50,000 in the UK in 2023. The RSPCA leads the 'Focus on Severe Suffering' initiative, which is endorsed by LASA, LAVA and the IAT. Its Roadmap to address severe suffering is widely supported by the scientific community.

Key points :

- The Roadmap is a user-friendly, practical exercise to help users focus on procedures undertaken within the establishment that could cause 'severe' suffering, identify contributing factors and find practical ways of avoiding or refining these.

- The Roadmap does not create any additional tasks for the AWERB or specific staff.

- It addresses the three main causes of severe suffering: severe disease models, cumulative effects and mortality (including unexpected mortality and animals 'found dead'), with guidance on reducing each one.

- The principles of the Roadmap can be applied to any level of suffering, not only 'severe'.

- The best starting point is an institutional agreement that reducing suffering at all levels is desirable, possible and deserving of the necessary attention, time and resources.

- The first step is to identify or establish the group that will conduct the ANALYSIS and set up the Roadmap process.

- The second step involves an EVALUATION to identify where 'severe' suffering is currently occurring, focusing on the three main reasons for severe suffering listed above.

- The third step is to IDENTIFY ISSUES. This includes implementing refinements that have been identified and using tailored welfare assessment protocols to evaluate whether these were effective in reducing suffering and improving welfare.

- The final step is to OVERCOME OBSTACLES, including reviewing your work and planning the next steps, as refinement is a continuous process.

- Depending on the establishment, it may be possible to set a stretch objective of aiming for a challenging but achievable time point after which no further severe studies would be undertaken.

Background information:

- **The Roadmap is a user-friendly, practical exercise to help users focus on procedures undertaken within the establishment that could cause 'severe' suffering, identify contributing factors and find practical ways of avoiding or refining these.** It has been developed with input from scientists, animal technologists and named persons, and AWERBs. You can find the Roadmap and its materials at focusonseveresuffering.co.uk/roadmap.

- **The Roadmap does not create any additional tasks for the AWERB or specific staff.** It provides a comprehensive, structured way to approach project design, refinement and welfare assessment - all tasks that have to be implemented - whilst helping to ensure that all factors and viewpoints have been taken into account, and records kept.

- **It addresses the three main causes of severe suffering, with guidance on reducing each one.** These are: (i) some procedures are inherently more likely to cause severe suffering; (ii) a combination of less severe factors can lead to an increase in overall suffering; often termed 'cumulative severity', (iii) if animals die, this may involve severe suffering – this includes both unexpected mortality, and 'death as an endpoint'.

- **The principles of the Roadmap can be applied to any level of suffering, not only 'severe'.** The approach of considering the animal's entire life experience, applying refinement at every stage, can be equally effectively applied to 'mild' and 'moderate' procedures.

- **The best starting point is an institutional agreement that reducing suffering at all levels is desirable, possible and deserving of the necessary attention, time and resources.** This is intrinsic to a good Culture of Care and can be initiated and led by the AWERB. A key principle of the Roadmap is an internal 'audit' of procedures, by an appropriate team of people with different expertise and perspectives.

- **The first step is to identify or establish the group that will conduct the ANALYSIS and set up the Roadmap process.** This could be the AWERB, a 3Rs sub-group, or a specially set up body. You could include the scientists undertaking the procedures, the veterinarian, animal technologists and 'named' persons, lay members, and external experts. The group will need i) a description of the proposed protocol, study or project; ii) the European Commission document on the severity assessment framework; and iii) the Roadmap sheet 1 - predicted lifetime experiences and sheet 2 - focus on procedures.

- **The second step involves an EVALUATION to identify where 'severe' suffering is currently occurring, focusing on the three main reasons for severe suffering listed above. The Roadmap includes downloadable sheets to help with this.**
  1. For severe disease models, the Roadmap provides guidance on searching for literature, and consulting colleagues, on refining the specific procedure in question.
  2. In the case of cumulative effects, comprehensive guidance and resources are provided to thoroughly review the animal's lifetime experiences, identifying every source of potential suffering and implementing refinement for each one (the Marginal Gains principle). Lifetime experiences include:

- Non-procedural effects (e.g. sourcing, transport, marking for identification): use <u>sheet 1 - predicted lifetime experiences</u>, the guidance notes and the <u>worked example</u> to discuss and predict what the animal could experience, what the welfare issues might be and how these could be mitigated.
- Procedural effects (e.g. drug administration): use <u>sheet 2 - focus on procedures</u>, with its <u>worked example</u>.

3. To help avoiding mortality, the Roadmap asks: i) is there a scientific requirement for death as an endpoint?; ii) is there a regulatory requirement for mortality?; and iii) is mortality difficult to predict in the strain or model? Guidance is provided for each scenario.

- **The third step is to IDENTIFY ISSUES. This includes implementing refinements that have been identified and using tailored welfare assessment protocols to evaluate whether these were effective in reducing suffering and improving welfare.** After refinements have been identified, at this stage they may be implemented or trialled whilst using tailored welfare assessment protocols to ensure their effectiveness. Indicators of pain, suffering or distress should be reliably recognisable, effective at providing robust information about the animal's welfare state, relevant to the study, species and strain, practical to carry out without disturbing the animal, and possible to consistently measure, interpret and analyse.. The European Commission guidance on severity assessment may be used as a template, with the help of Sheets 1 and 2 after they have been completed.

- **The final step is to OVERCOME OBSTACLES, including reviewing your work and planning the next steps, as refinement is a continuous process.** At this point, you may have: set out a plan to retrieve information on refining inherently severe protocols; reviewed lifetime experiences and the potential impact on animals; worked through sheets 1 and 2; identified refinements, humane endpoints, and welfare indicators; set out a plan to review and optimise the welfare assessment and recording system; planned to act on mortality; and decided outputs, e.g. feedback to the regulator, or edits to the project proposal form. As part of the next steps, it is important to consider how the outcomes of this exercise will be captured and communicated to all relevant people.

- **Depending on the establishment, it may be possible to set a stretch objective of aiming for a challenging but achievable time point after which no further severe studies would be undertaken.** Having a fixed point in time to work towards can be a powerful motivating force for achieving challenging, yet achievable, goals.

- We have received positive feedback about the Roadmap from many individuals and organisations, who have used it to significantly refine procedures, resulting in clear reductions in 'severe' suffering (and some have also used the approach to refine 'moderate' procedures). We are keen to receive further feedback at <u>animalsinscience@rspca.org.uk</u> and have also run user sessions at establishments - requests can be made at the above email address.

For more information, visit the Roadmap section on the Focus on Severe Suffering <u>website</u>.

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