Research and management of wild animals:

Politics, ethics and the 3Rs

Adrian Smith & Jon M. Arnemo
adrian.smith@norecopa.no

norecopa

norecopa.no/wild

Harmonisation of the Care and Use of Wild and Domestic Mammals and Birds in Field Research, Gardermoen, 26 - 27 October 2017
norecopa.no/media/7996/arnemo.pdf

International consensus meetings

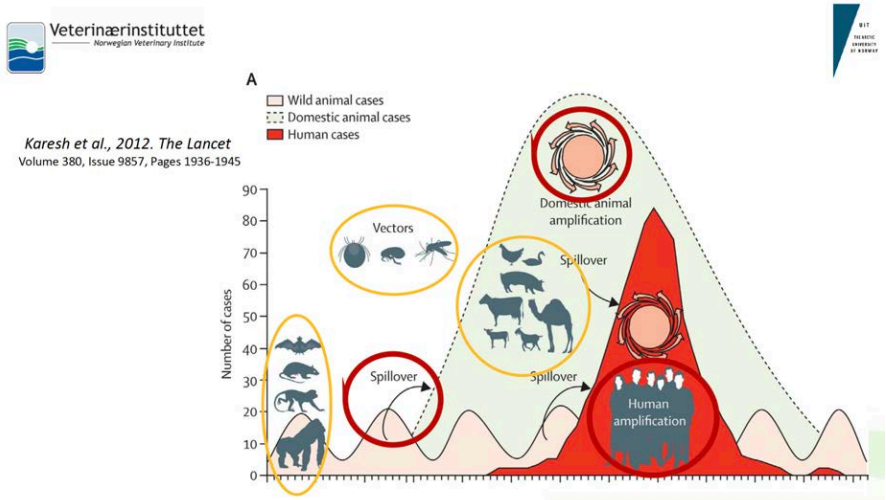
Harmonisation of the Care and Use of:

- *Fish (2005)*
- *Wildlife (2008)*
- *Fish (2009)*
- *Agricultural animals (2012)*
- *Animals in Field Research (October 2017)*

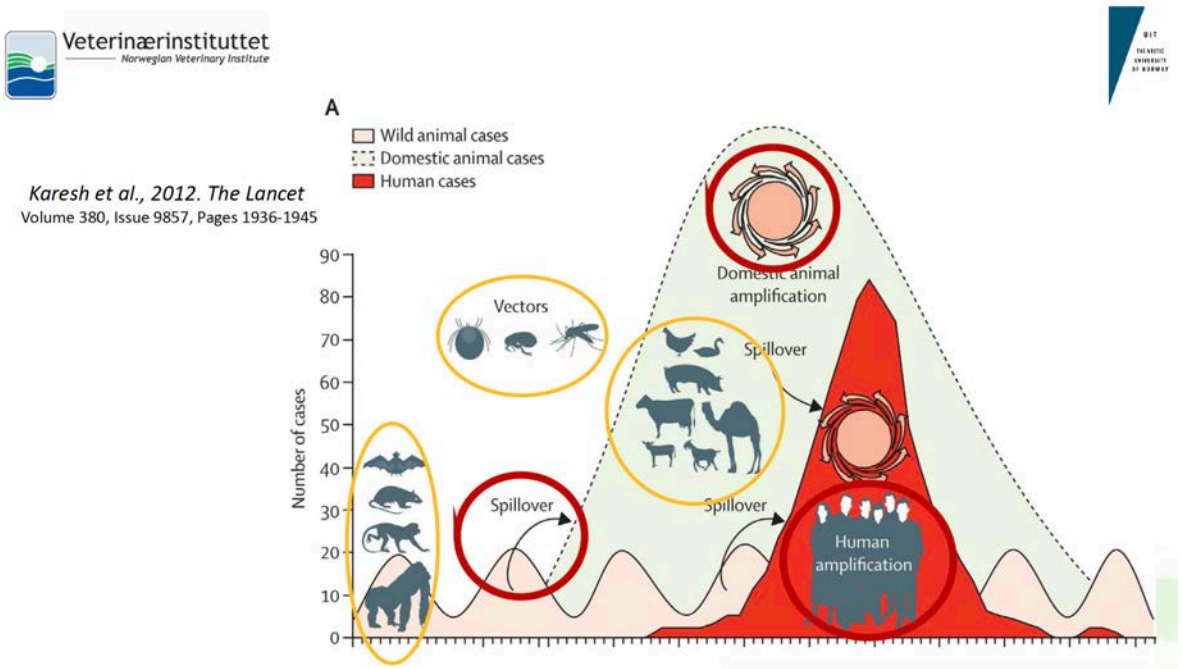
https://norecopa.no/meetings

All presentations and consensus statements are on the internet: a lasting resource

'Wildlife research is now recognised as part of the One Health concept, as the study of disease transmission and population movements becomes more important'



From Carlos das Nevas: https://norecopa.no/media/8059/carlos-das-neves.pdf



From Carlos das Nevas: https://norecopa.no/media/8059/carlos-das-neves.pdf

Some of the major challenges

- ❑ Research or Population Management?
- ❑ Severity assessment
- ❑ The role of the veterinarian
- ❑ Education and competence
- ❑ Dissemination of advances within the 3Rs

Research or Population Management?

- The distinction is important because it often decides whether or not the research animal legislation and competent authority are involved

reuters.com/journalists/enrique-marcarian

Research or Population Management?

- Permission?

bobhayesyukon.com

Research or Population Management?

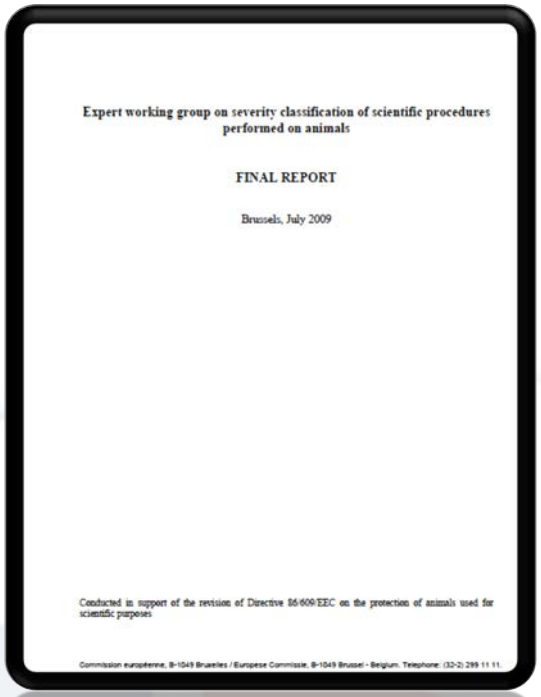
- Capture of wild animals shall be carried out only by competent persons using methods which do not cause the animals avoidable pain, suffering, distress or lasting harm (article 9(3), 2010/63)
- Capture *per se* (regardless of the purpose) is not a regulated procedure when performed by competent persons using methods which do not cause avoidable pain, suffering, distress or lasting harm *(is this possible from a helicopter?)*
- 2010/63 does not apply to practices undertaken for the primary purpose of identification of an animal (article 1.5(3). Bird ringing is used as an example.
- The use of anaesthesia in itself is likely to be a regulated procedure
- Can the animal instead be tracked by non-invasive methods? (visual observations, footprints, DNA analysis of faeces)
- But usually data is collected which subsequently can be used for scientific research
- If these samples are taken for a scientific purpose by a method which reaches the Directive's threshold, then the procedure falls within the scope
- Regardless, who conducts a harm-benefit assessment?
- Does the wolf experience any difference?

Role of the veterinarian?

- 2010/63 states that handling of animals should be carried out by 'competent persons', not specifically with veterinary training (articles 9-3 and 23).
- Norwegian legislation on animal research accepts that non-veterinarians can chemically immobilise animals provided that they have received sufficient training and have demonstrated their competence – but this is normally performed in facilities where veterinarians can intervene quickly if necessary.
- In Norway, the competent authority in general demands that veterinarians perform chemical immobilisation of *wildlife*. In addition, the medicines agency demands that certain drugs are administered by veterinarians.
- This can lead to practical problems in performing wildlife research in remote areas, and raises the question as to whether non-veterinarians have the necessary competence and equipment to tackle emergencies.
- Prescription of drugs for immobilisation involves compliance with other legislation – and in the case of accidents, a veterinarian or PI may be the one who has to take the responsibility.

Some examples...

Severity classification



ENVIRONMENT

European Commission

European Commission > Environment > Chemicals > Animals used for scientific purposes

Expert Working Group report on severity classification

http://ec.europa.eu/environment/chemicals/lab_animals/pdf/report_ewg.pdf

Working Party Report

Guidance on the severity classification of scientific procedures involving fish: report of a Working Group appointed by the Norwegian Consensus-Platform for the Replacement, Reduction and Refinement of animal experiments (Norecopa)

P Hawkins (Convenor)[1], N Dennison[2], G Goodman[3], S Hetherington[4], S Llywelyn-Jones[5], K Ryder[2] and A J Smith[6]

[1]Research Animals Department, RSPCA, Wilberforce Way, Southwater, West Sussex RH13 9RS, UK, [2]Animals (Scientific Procedures) Inspectorate, Home Office, PO Box 677[illegible] Dundee DD1 9WW, UK, [3]Biological Services, The University of Edinburgh, Chancellor Building, 49, Little France Crescent, Edinburgh EH16 4SB, UK, [4]CEFAS, Pakefield Road, Lowestoft, NR33 0HT, UK, [5]King's College London, Biological Services Unit, 4th floor, Hodgkin Building, Guy's Campus, London SE1 1UL, UK, [6]Norecopa, c/o Norwegian Veterinary Institute, PO Box 750 Sentrum, N-0106 Oslo, Norway
Corresponding author: P Hawkins. Email: phawkins@rspca.org.uk

Abstract

The severity classification of procedures using animals is an important tool to help focus the implementation of refinement and to assist in reporting the application of the 3Rs (replacement, reduction and refinement). The recently revised Directive that regulates animal research and testing within the European Union requires Member States to ensure that all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe', using assignment criteria set out by the European Commission (EC). However, these are focused upon terrestrial species, so are of limited relevance to fish users. A Working Group set up by the Norwegian Consensus-Platform for the 3Rs (Norecopa) has produced guidance on the classification of severity in scientific procedures involving fish, including examples of 'subthreshold', 'mild', 'moderate', 'severe' and 'upper threshold' procedures. The aims are to complement the EC guidelines and help to ensure that suffering in fish is effectively predicted and minimized. Norecopa has established a website (www.norecopa.no/categories) where more information on severity classification for procedures using fish, including field research, will be made available.

Keywords: Fish, harm–benefit assessment, humane endpoints, refinement, severity

Laboratory Animals 2011; 1–6. DOI: 10.1258/la.2011.010181

Background

An effective prediction of the effects of a research protocol on the animals concerned helps to ensure that any pain, suffering or distress they may experience will be effectively anticipated, recognized and alleviated. This is essential not only for animal welfare but also for scientific validity, because physiological and behavioural responses to suffering can significantly affect data quality. Severity classification is thus an important tool to help focus the implementation of refinement, including monitoring its progress, and to assist in reporting the application of the 3Rs (replacement, reduction and refinement) of Russell and Burch,[1] which is now an integral part of the legislation on animal research and testing in many countries. Predictions of severity are also fundamental to the harm–benefit assessments undertaken by bodies such as regulatory authorities and ethical committees when deciding whether or not a project should be licensed or funded.

There may also be a legal requirement to predict and classify severity. For example, the new Directive regulating animal use within the European Union, which must be implemented within all Member States by January 2013, requires the severity of each procedure to be classified on the basis of the 'degree of pain, suffering, distress or lasting harm expected to be experienced by an individual animal during the course of the procedure', with the aim of enhancing transparency, facilitating the project authorization process and providing tools for monitoring compliance.[2] Member States will have to ensure that 'all procedures are classified as 'non-recovery', 'mild', 'moderate' or 'severe' on a case-by-case basis, using the assignment

Guidance on the severity classification of procedures involving fish

Report from a Working Group
convened by Norecopa

P Hawkins, N Dennison, G Goodman, S Hetherington,
S Llywelyn-Jones, K Ryder and AJ Smith

Laboratory Animals, 45: 219-224, 2011

Severity classification for procedures in field research...?

photo: Svalbardposten

SMERTER: Denne villreinen måtte avlives i Nordfjella. En isklump på GPS halsbåndet hadde vokst seg større enn hodet på reinen.

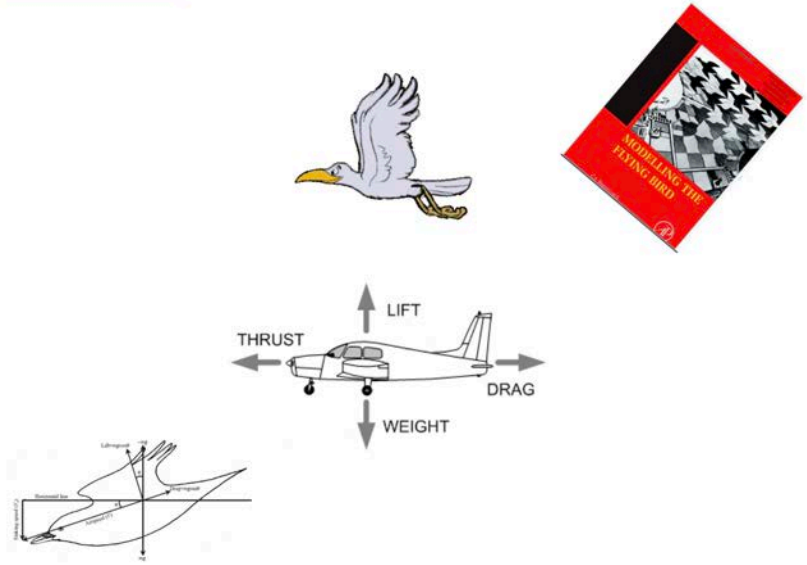
Av TOR-HARTVIG BONDØ og LINN K. YTTERVIK
(VG) 22.01.2016 20:27 49

annonse

photo: vg.no

The use of transmitters

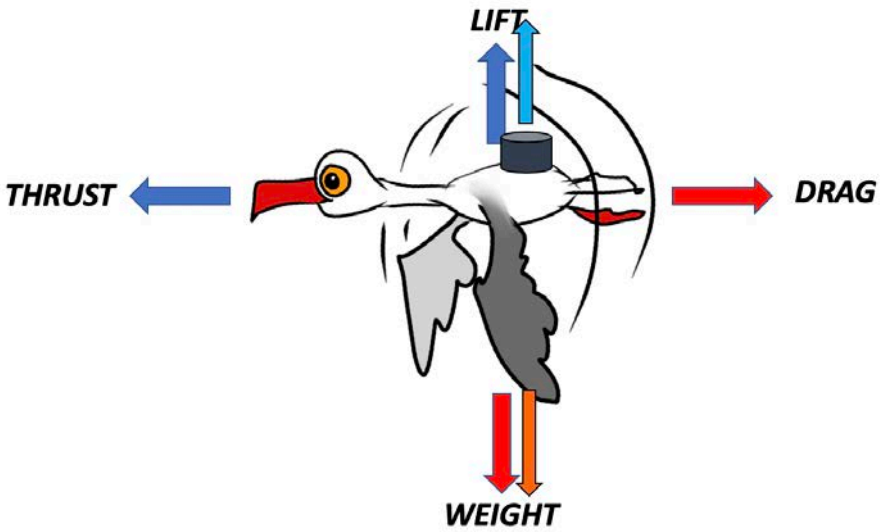
Primary effects Flight forces - Birds are just glorified planes



From Rory Wilson: norecopa.no/media/8018/rory-wilson.pdf

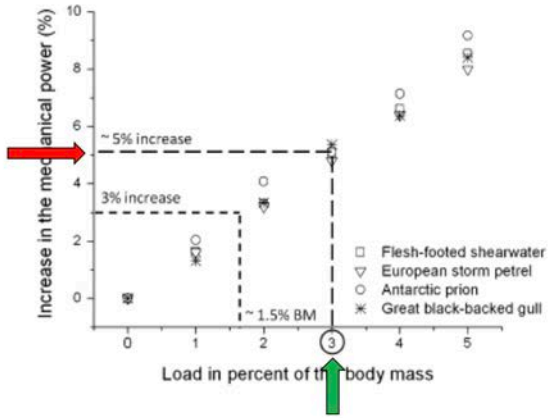
Primary effects

The increased lift balances the extra force from the tag weight



From Rory Wilson: norecopa.no/media/8018/rory-wilson.pdf

Not least;
because tag detriment does not always scale linearly with mass



Vandenabeele *et al.*, 2011

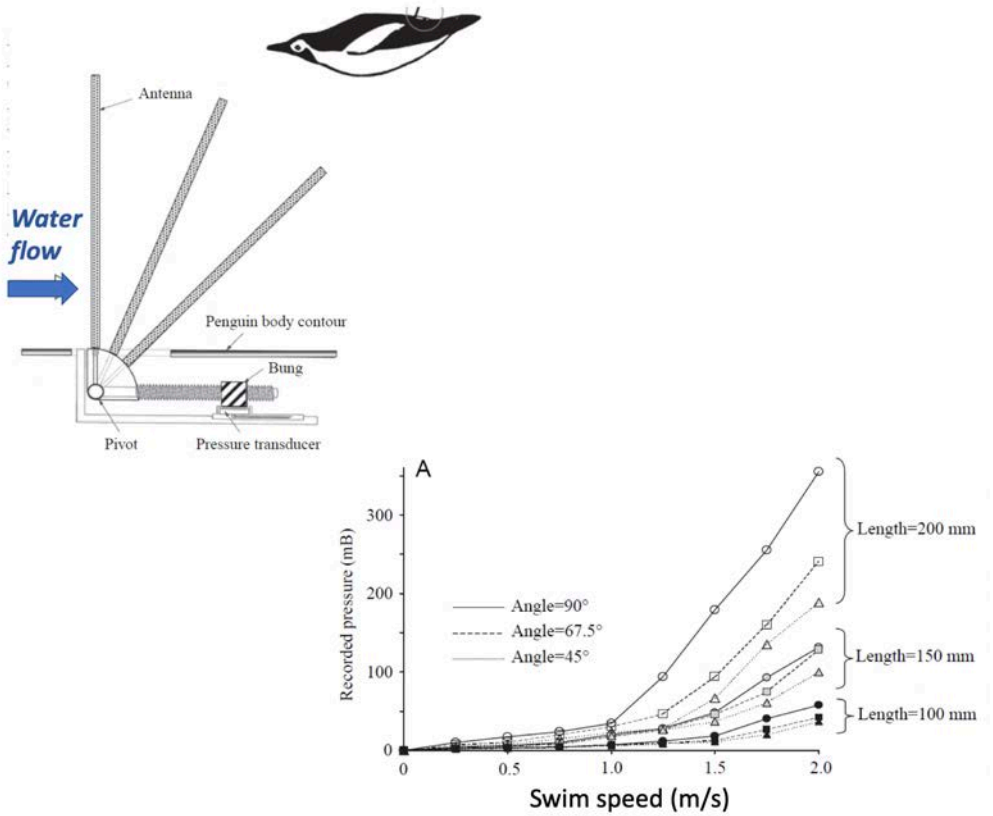
From Rory Wilson: norecopa.no/media/8018/rory-wilson.pdf

Drag occurs in water as well as in the air...

Photo: T. Poppe, NMBU

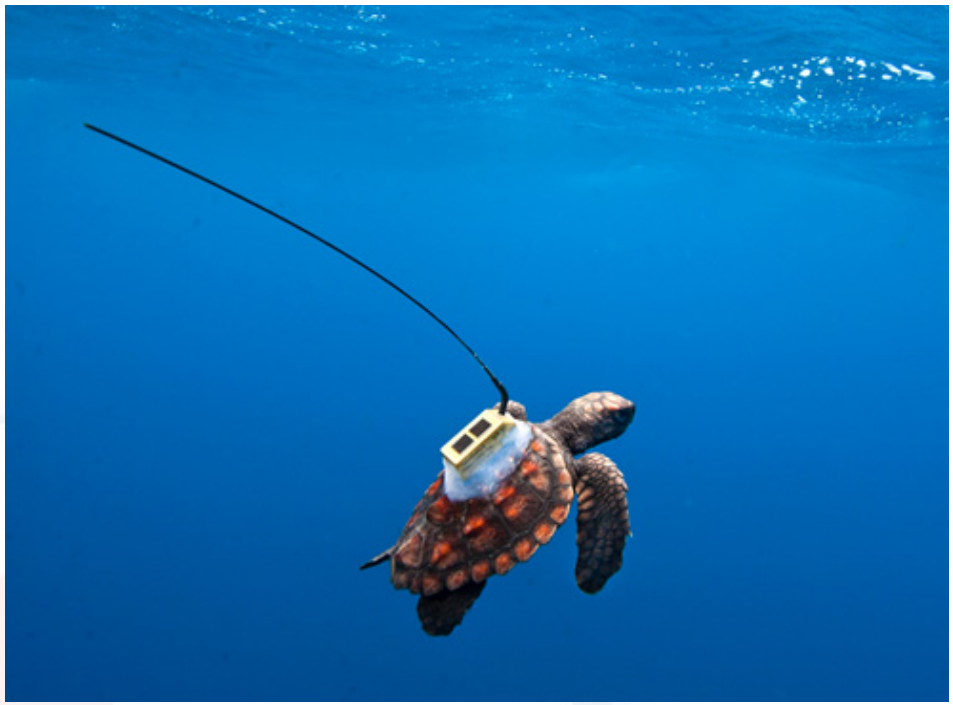
http://blogs.discovermagazine.com/notrocketscience/2011/01/12/flipper-bands-impair-penguin-survival-and-breeding-success/#.VLU6_8Y7_wo

Drag occurs in water as well as in the air...



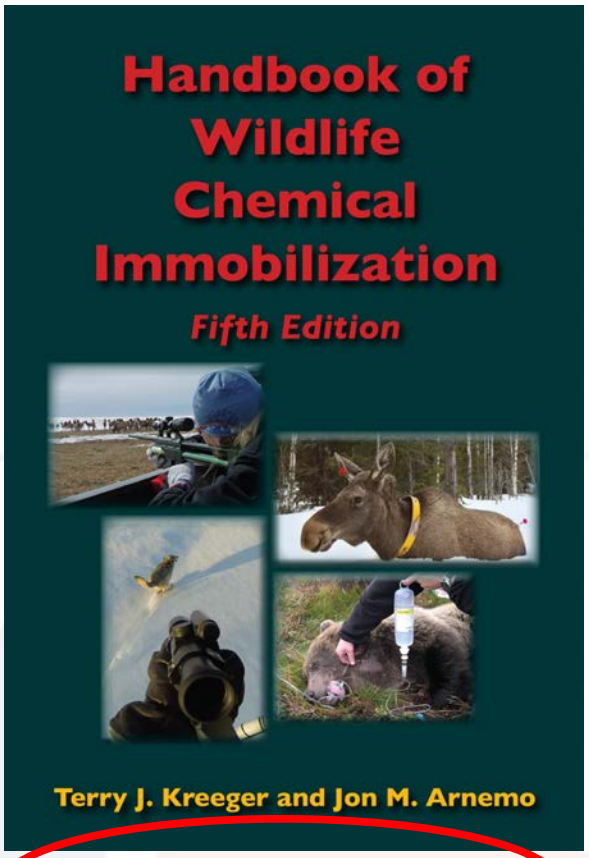
From Rory Wilson: norecopa.no/media/8018/rory-wilson.pdf

Drag occurs in water as well as in the air...



From Rory Wilson: norecopa.no/media/8018/rory-wilson.pdf

Sharing best practice



norecopa.no/Arnemo

A 4th R: REALITY (John Linnell)
Captures in real life

From Jon M. Arnemo: norecopa.no/media/7996/arnemo.pdf

Monitoring, emergencies & treatment

From Jon M. Arnemo: norecopa.no/media/7996/arnemo.pdf

Equipment

- Handling (eye oinment & cover)
- Carrying and positioning
- Vitals (T, HR, RR, CRT)
- Anesthetic depth (safety)
- Blood oxygenation (pulse oximeter)
- Blood gases (iStat)
- Oxygen (tubes or concentrator)
- ET tubes, bag
- Heart monitor (ECG)
- Blood pressure
- Stomach tube, rumen trochar
- Fluids, IV line
- Surgical kit (wound treatment)
- Antibiotics, emergency drugs
- Euthanasia (firearm, drugs)

From Jon M. Arnemo: norecopa.no/media/7996/arnemo.pdf

Action Points from the Consensus Meeting:

- ❑ Ensure that decisions on capture, marking and tracking are made with input from the central animal research authorities, regardless as to whether it is science or management
- ❑ More species- and situation-specific guidelines need to be developed, and the National Committees must share best practice
- ❑ Capture and restraint should be reduced to a minimum, and their replacement by non-invasive methods encouraged
- ❑ Pay more attention to the effects of external devices
- ❑ Liase with industry to produce better devices
- ❑ Create an accessible inventory of field methods
- ❑ Collect examples of severity classification
- ❑ Develop more modules for education in field research

Who should be doing what?

Regulators:

- ❑ Work with other competent authorities to decide whether procedures fall within the scope of 2010/63, or within the jurisdiction of other legislation
- ❑ Share best practice nationally and internationally

Who should be doing what?

Field researchers:

- ❑ Ensure implementation of the legislation
- ❑ Encourage harm-benefit assessment, even if the procedure falls outside the scope of 2010/63
- ❑ Apply the 3Rs systematically at all stages
- ❑ Promote advances in the 3Rs at their scientific meetings
- ❑ Publish failures as well as successes

Who should be doing what?

Norecopa *(and therefore also other 3R Centres)*:

- ❑ Arrange regular meetings with all stakeholders
- ❑ Collect, review and stimulate the production of guidelines and protocols
- ❑ Encourage other 3R Centres to do the same

norecopa.no/PREPARE

A downloadable checklist

OB4S3 Wed.

PREPARE

norecopa

The PREPARE Guidelines Checklist

Planning Research and Experimental Procedures on Animals: Recommendations for Excellence

Adrian J. Smith[a], R. Eddie Clutton[b], Elliot Lilley[c], Kristine E. Aa. Hansen[d] & Trond Brattelid[e]

[a]Norecopa, c/o Norwegian Veterinary Institute, P.O. Box 750 Sentrum, 0106 Oslo, Norway; [b]Royal (Dick) School of Veterinary Studies, Easter Bush, Midlothian, EH25 9RG, U.K.; [c]Research Animals Department, Science Group, RSPCA, Wilberforce Way, Southwater, Horsham, West Sussex, RH13 9RS, U.K.; [d]Section of Experimental Biomedicine, Department of Production Animal Clinical Sciences, Faculty of Veterinary Medicine, Norwegian University of Life Sciences, P.O. Box 8146 Dep., 0033 Oslo, Norway; [e]Division for Research Management and External Funding, Western Norway University of Applied Sciences, 5020 Bergen, Norway.

PREPARE[1] consists of planning guidelines which are complementary to reporting guidelines such as ARRIVE[2].
PREPARE covers the three broad areas which determine the quality of the preparation for animal studies:

1. **Formulation of the study**
2. **Dialogue between scientists and the animal facility**
3. **Quality control of the components in the study**

The topics will not always be addressed in the order in which they are presented here, and some topics overlap. The PREPARE checklist can be adapted to meet special needs, such as field studies. PREPARE includes guidance on the management of animal facilities, since in-house experiments are dependent upon their quality. The full version of the guidelines is available on the Norecopa website, with links to global resources, at **https://norecopa.no/PREPARE**.
The PREPARE guidelines are a dynamic set which will evolve as more species- and situation-specific guidelines are produced, and as best practice within Laboratory Animal Science progresses.

Topic	Recommendation
(A) Formulation of the study	
1. Literature searches	☐ Form a clear hypothesis, with primary and secondary outcomes. ☐ Consider the use of systematic reviews. ☐ Decide upon databases and information specialists to be consulted, and construct search terms. ☐ Assess the relevance of the species to be used, its biology and suitability to answer the experimental questions with the least suffering, and its welfare needs. ☐ Assess the reproducibility and translatability of the project.
2. Legal issues	☐ Consider how the research is affected by relevant legislation for animal research and other areas, e.g. animal transport, occupational health and safety. ☐ Locate relevant guidance documents (e.g. EU guidance on project evaluation).
3. Ethical issues, harm-benefit assessment and humane endpoints	☐ Construct a lay summary. ☐ In dialogue with ethics committees, consider whether statements about this type of research have already been produced. ☐ Address the 3Rs (replacement, reduction, refinement) and the 3Ss (good science, good sense, good sensibilities). ☐ Consider pre-registration and the publication of negative results. ☐ Perform a harm-benefit assessment and justify any likely animal harm. ☐ Discuss the learning objectives, if the animal use is for educational or training purposes. ☐ Allocate a severity classification to the project. ☐ Define objective, easily measurable and unequivocal humane endpoints. ☐ Discuss the justification, if any, for death as an end-point.
4. Experimental design and statistical analysis	☐ Consider pilot studies, statistical power and significance levels. ☐ Define the experimental unit and decide upon animal numbers. ☐ Choose methods of randomisation, prevent observer bias, and decide upon inclusion and exclusion criteria.
(B) Dialogue between scientists and the animal facility	
5. Objectives and timescale, funding and division of labour	☐ Arrange meetings with all relevant staff when early plans for the project exist. ☐ Construct an approximate timescale for the project, indicating the need for assistance with preparation, animal care, procedures and waste disposal/decontamination. ☐ Discuss and disclose all expected and potential costs. ☐ Construct a detailed plan for division of labour and expenses at all stages of the study.
6. Facility evaluation	☐ Conduct a physical inspection of the facilities, to evaluate building and equipment standards and needs. ☐ Discuss staffing levels at times of extra risk.
7. Education and training	☐ Assess the current competence of staff members and the need for further education or training prior to the study.
8. Health risks, waste disposal and decontamination	☐ Perform a risk assessment, in collaboration with the animal facility, for all persons and animals affected directly or indirectly by the study. ☐ Assess, and if necessary produce, specific guidance for all stages of the project. ☐ Discuss means for containment, decontamination, and disposal of all items in the study.
(C) Quality control of the components in the study	
9. Test substances and procedures	☐ Provide as much information as possible about test substances. ☐ Consider the feasibility and validity of test procedures and the skills needed to perform them.
10. Experimental animals	☐ Decide upon the characteristics of the animals that are essential for the study and for reporting. ☐ Avoid generation of surplus animals.
11. Quarantine and health monitoring	☐ Discuss the animals' likely health status, any needs for transport, quarantine and isolation, health monitoring and consequences for the personnel.
12. Housing and husbandry	☐ Attend to the animals' specific instincts and needs, in collaboration with expert staff. ☐ Discuss acclimatization, optimal housing conditions and procedures, environmental factors and any experimental limitations on these (e.g. food deprivation, solitary housing).
13. Experimental procedures	☐ Develop refined procedures for capture, immobilisation, marking, and release or rehoming. ☐ Develop refined procedures for substance administration, sampling, sedation and anaesthesia, surgery and other techniques.
14. Humane killing, release, reuse or rehoming	☐ Consult relevant legislation and guidelines well in advance of the study. ☐ Define primary and emergency methods for humane killing. ☐ Assess the competence of those who may have to perform these tasks.
15. Necropsy	☐ Construct a systematic plan for all stages of necropsy, including location, and identification of all animals and samples.

References

1. Smith AJ, Clutton RE, Lilley E, Hansen KEA & Brattelid T. PREPARE: Guidelines for Planning Animal Research and Testing. *Laboratory Animals*, 2017. DOI: 10.1177/0023677217724823.
2. Kilkenny C, Browne WJ, Cuthill IC *et al.* Improving Bioscience Research Reporting: The ARRIVE Guidelines for Reporting Animal Research. *PloS Biology*, 2010; DOI: 10.1371/journal.pbio.1000412.

Further information
https://norecopa.no/PREPARE | *post@norecopa.no* | @norecopa

Translated so far into 19 languages

General conclusions

- ❑ Communicate
- ❑ Show mutual respect and humility
- ❑ Avoid turning this into a conflict of professions
- ❑ Agree upon implementation of the 3Rs
- ❑ PREPARE
- ❑ Be transparent about the results
- ❑ Share best practice nationally and internationally

Thanks to Norecopa's main sponsors:

- Standing Committee on Business Affairs, Norwegian Parliament
- Norwegian Ministries of Agriculture and Fisheries
- Research Council of Norway
- Laboratory Animals Ltd.
- Nordic Society Against Painful Experiments (NSMSD)
- Norwegian Society for Animal Protection
- Novo Nordisk
- Scottish Accreditation Board
- Stiansen Foundation
- Universities Federation for Animal Welfare (UFAW)
- US Department of Agriculture

norecopa.no

norecopa.no/wild