Harm-Benefit Assessment

an update from
AALAS-FELASA WG on Harm-Benefit Analysis

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Assessment

Plan

- Background of Harm-Benefit Analysis (HBA)
- The AALAS/FELASA Working Group on HBA
- Harms and benefits and ways to compare these
- Summary of HBA
- Harm-benefit assessment in practice
  - Presentation of The "Tool"

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How do we justify use of animals?

- Use of animals in research is justified by the utility for humans
  - Use of animals is justified because of the "greater good for the majority" – the basic principle of utilitarian ethics
  - The proper course of action is the one that maximizes utility
- Harm Benefit analysis is based on utilitarian consequence ethics
  - We weigh the harm of animal against benefit of a good purpose

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PUBLIC OPINION IN SWEDEN ON
THE USE OF ANIMALS IN RESEARCH

Vetenskapsrådet

VETENSKAPSRÅDETS RAPPORTSERIE   8:2008

Animal experiments can be acceptable in the following context and conditions

- *If it involves medical research (benefit)*
- *If it involves serious/severe disease (benefit)*
- *If the animals do not suffer (harm)*

http://www.vr.se/inenglish/fromus/news/newsarchive/news2008/news2008/
publicopinioninswedenontheuseofanimalsinresearch.5.1d4cbbbb11a00d342b0800010843.html

Painful dilemmas: A study of the way the public's assessment of animal research balances costs to animals against human benefits. Lund TB1, Mørkbak MR, Lassen J, Sandøe P. Public Understanding of Science 2014, Vol. 23(4) 428–444

Table 4. Cost–benefit decisions among the attitude stances displayed by accumulated approval rates in percentages.

	Approvers[a]	Reserved[b]	Disapprovers[c]
Purpose[d]			
Approval of research when pigs experience moderate pain			
Cancer	96%	69%	23%
Cardio-vascular	94% [n.s.]	72% [n.s.]	22% [n.s.]
Migraine	91% [n.s.]	58% *	28% [n.s.]
Obesity	80% **	46% **	24% [n.s.]
Cosmetic testing	55% **	31% **	12% [n.s.]

animal are fixed (cardio-vascular research using mice). Table 4 reports results on these two situations. The findings displayed in it suggest quite forcefully that cost–benefit decisions are being
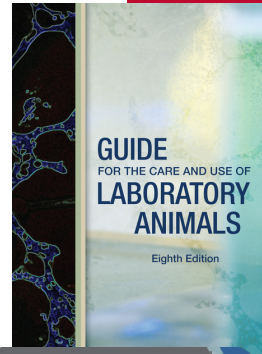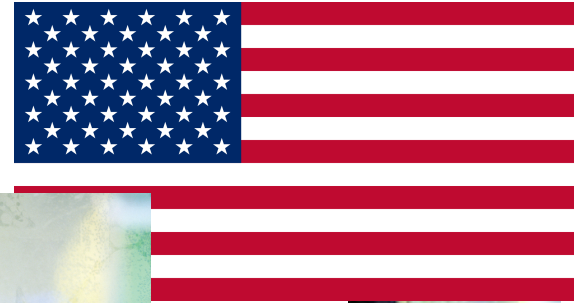
"The findings displayed suggest that cost-benefit decisions are being applied.
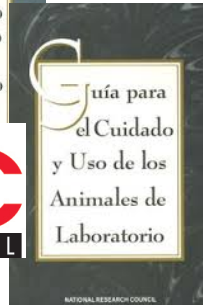*Furthermore, this is the case in all attitude stances"*

animal or do so only moderately. Thus, looking at purpose, where moderate pain in pigs is involved,

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EU directive 2010/63

National Institutes of Health

CIOMS

ICLAS

OiE

Several important organizations emphasize the importance of harm-benefit assessment in their written ethical guidelines for use of animals in research

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What is a harm-benefit analysis?

And how do you do HBA?

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AALAS/FELASA Harm-Benefit assessment WG
set down by the AALAS - FELASA liaison body

AALAS

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AALAS-FELASA WG on H-B Analysis
Terms of Reference

1. Review existing literature on harm-benefit analysis.
2. Define and describe the current concepts and elements of the harm-benefit analysis.
3. Recommend how it can be addressed by persons responsible of the protocol/project applications.
4. Define how the harm-benefit analysis can be implemented by committee members as part of the ethical evaluation.
5. Present practical cases that may exemplify common situations in the research environment.

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Harm-Benefit Analysis: An Ethical Framework for conducting Humane Animal Research

Short introduction to the AALAS-FELASA WG on Harm-Benefit Analysis

1. Review existing literature on harm-benefit analysis.
2. Define and describe the current concepts and elements of the harm-benefit analysis.

- Harm/Cost-Benefit analysis in LAS
- Harm/Cost-Benefit analysis in human medical trials
- Risk-Benefit analysis in other industries or fields
- Guidelines and policy statements on use of animals in research and education (by for example CIOMS, ICLAS, OIE, US Government, European commission, FELASA, AALAS)

- How are harms and benefits defined?
- How are harms and benefits balanced or compared?

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Pain

Pain has been main focus in addressing harm!

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- "Can animals feel ain?" - Pain theory. Descartes

2015

"Animals experience pain in a similar manner as human"! (2015)

- Pain can and should be controlled by use of modern anesthetics and analgesics.

Dimensions of harm
identified in the literature reviewed

- **Species**, choice of animals
- Sentience and consciousness
- Quality of animals
- Duration of experiment
- Duration related to lifespan
- **Number** of animals
- Origin, acquisition or transport
- Care, housing factors, handling, health care
- Possibility to express Normal Behaviour
- **Staff** competence and quality
- Hunger and Thirst

- Discomfort
- **Pain**
- Injury or Disease
- Fear, anxiety and distress
- Frequency of procedures
- Severity of procedures
- Risk of harm = probability x severity
- Deaths (caused by the experiment)
- Intrinsic value and animal rights
- Genetic modulation of animals - respect for nature
- **Aim, Realistic potential**
- **Scientific Quality**
- **Non-publishing of negative results**

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Dimensions of benefit
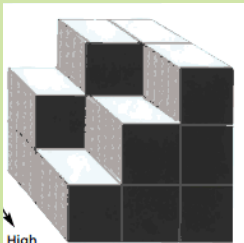
identified in the literature reviewed

- **Benefits for humans**
- **Benefits for animals**
- **Benefits for environment**

- **Health interests**
- **Safety interests**
- **Knowledge interests**
- **Educational interest**
- Economic interests

- **What-who-how-when**

- Primary (direct) versus secondary (indirect) benefits

- "Surrogate outcomes" versus "health outcomes"
- Originality
- Dissemination of results
- **Aim, Realistic potential**
- **Quality, "good science"**
- **Non-publishing of negative results**

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Models for Harm-Benefit Analysis

- Algorithm models
- Graphic representations
- Process oriented models

- The "need" for categorization

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Summary - Models for Harm-Benefit Analysis

	Strengths	Weaknesses
Categories (Tables, spreadsheets)	**Categories** are useful to simplify a complex picture. Identify severe categories and stimulate actions to avoid them.	The categories do not fit all cases
$E = mc^2$ $\Sigma = \pi e^{HBA}$	**Algorithms** are helpful in guiding a decision	Moral dilemmas cannot/shall not be solved by arithmetic's
	Graphic representations have pedagogic value in visualizing the concept and relationship between harm and benefit	Depend on defined categories Not operational
	Process oriented models structure the HBA process, how to balance different opinions and question quality of the analysis. Generic	Does not provide an answer on what model to use or provide solutions for conclusions

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Harm-Benefit Analysis "extensive" Summary

- HBA is a <u>systematic</u> way to assess and compare harms, benefits and how they are balanced

- HBA must be <u>transparent</u>

- HBA provides an <u>essential part of the ethical review</u>

- HBA is based on <u>utilitarian consequence ethics</u>

- HBA <u>justifies use of animals because of potential benefit</u>

- HBA <u>identifies harm</u> – and <u>stimulate</u> researchers to seek alternative approaches

- HBA <u>clarifies</u> if harm is <u>necessary</u> for achieving certain benefits

- HBA <u>stimulates</u> <u>ethical reflection and discussion</u>

- HBA is important to <u>avoid uncritical use</u> of animals even for the cause of the good

- HBA is important for <u>public relations</u>

- HBA is dependent on and limited to the current <u>context</u> (external factors)

- HBA is influenced by <u>subjective opinions</u> ("affective heuristics")

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Harm-Benefit Analysis in a nutshell ("short summary")

- **What are you going to do?**
  - **What is the impact on the animals? (harm)**

- **Why are you going to do it?**
  - **What are the objectives? (benefits)**

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3. Recommend how it can be addressed by persons responsible of the protocol/project applications.
4. Define how the harm-benefit analysis can be implemented by committee members as part of the ethical evaluation

Harm - 5 Freedoms

1. Freedom from Hunger and Thirst
2. Freedom from Discomfort
3. Freedom from Pain, Injury or Disease
4. Freedom to Express Normal Behaviour
5. Freedom from Fear and Distress

> ***Mellor&Reid, Concepts of animal well-being and predicting the impact of procedures on experimental animals (1994)***

"There is a danger that with focus largely on suffering we could overlook a broader view of welfare which may be more informative and safeguard more effectively the interests of the experimental animals "

The benefits

Kate Chandler, BVetMed MRCVS, DipECVN, PhD Principal Inspector (ASRU) April 2014 - **Harm-Benefit Analysis in the UK: 1986-2013 and beyond**

What?
- Scientific outputs
- (short/long-term)

Who?
- Patients
- Other researchers

How?
- Improved therapy, survival

When?
- In life-time of project
- Much later

Home Office

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Foto: Aurora Brønstad