The European Federation of the Pharmaceutical Industry and Associations' Research and Animal Welfare Group: Assessing and benchmarking 'Culture of Care' in the context of using animals for scientific purpose

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Abstract

The European Federation of Pharmaceutical Industries and Associations' Research and Animal Welfare group members reflected on the concept of a Culture of Care in relation to animal care and use and on differences in its understanding and application across European pharmaceutical companies. The term 'Culture of Care' is used across different regions and organizations but rarely with any defined indicators to support working practice.

The European Federation of Pharmaceutical Industries and Associations' Research and Animal Welfare group has developed a framework to help organizations identify gaps or potential areas for improvement in support of a positive Culture of Care.

The framework is a tool that identifies five areas of focus for a Culture of Care: company values; strategic approach at establishment level; implementation structures; staff support; and animal care and procedures. The framework is intended as an aid for continuous improvement, highlighting where indicators of good practice are present. We expect it to provide points of reflection and ideas for those looking to implement a Culture of Care in a structured way, while facilitating a professional and strategic approach. To prevent it supporting a 'tick-box' exercise, the framework must not be used as an auditing tool, but as a starting point for consideration and discussion about how care manifests within the context and constraints of individual establishments.

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Introduction

The European Federation of Pharmaceutical Industries and Associations (EFPIA) represents the pharmaceutical industry operating in Europe.

The EFPIA Research and Animal Welfare (RAW) group's remit includes:

- Horizon scanning of animal research including the political, legal and regulatory environment.

- Promoting implementation and good practice sharing of the Replacement, Reduction, Refinement (3Rs) and Culture of Care to support Directive 2010/63/EU and Commission reports.
- Communication about the pharmaceutical sector's 3R activities.

The term Culture of Care in the context of using animals in scientific research describes the culture in an organization that provides support to all staff to strive for continuous improvement in:

- animal care and welfare;
- care and welfare of staff involved in the animal care and use programme;
- scientific quality; and
- openness and transparency.

The European Union Directive 2010/63/EU[1] (referenced as the Directive hereafter) on the protection of animals used for scientific purposes does not mention Culture of Care specifically; however, there is a need for an animal welfare body (AWB) to foster a 'climate of care' (Recital 31). However, other guidance documents produced by the European Commission along with member states and stakeholders do refer to a Culture of Care. For example, the Education and Training Framework[2] includes the responsibility to champion a 'Culture of Care' among staff at all levels in the section on person(s) responsible for overseeing the welfare and care of animals in Article 24(1)(a). Furthermore, the guidance on inspections and enforcement[3] includes a Culture of Care in other functions of the inspection programme, providing guidance on factors to consider in determining the Culture of Care in an establishment and using inspectors or inspections to promote a Culture of Care.

The European Commission has produced a guidance document that has been endorsed by the national competent authorities, called '*A working document on Animal Welfare Bodies and National Committees to fulfil the requirements under the Directive*'.[4] In the introduction to this document it states National Committees play a fundamental role in 'establishing and maintaining an appropriate climate of care, often called in practice, and subsequently referred to in this document as a "Culture of Care".' AWB's also play a fundamental role in establishing and maintaining an appropriate Culture of Care. There is a section later in the document entitled 'Fostering a Culture of Care'. Fostering or promoting a Culture of Care is recognized as one of the benefits of an effective AWB.

A Culture of Care goes beyond adhering to legal requirements. It refers to an organizational culture that supports and values caring and respectful behaviour towards animals and co-workers. A Culture of Care is

the responsibility of everyone involved with animal studies, from those directly working on the studies and beyond to include animal facility management, sample analysts, study planners, engineers, biologists, chemists, statisticians, project leaders, managers and senior leaders. The culture should instil responsibility and accountability in those planning and implementing research programmes and those caring for animals, so they do the right thing ethically and strive for continuous improvement. A number of these structural and behavioural attributes are well described in The Guiding Principles on Good Practice for United Kingdom (UK) Animal Welfare and Ethical Review Bodies.[5] However, having a practical framework underpinning these attributes would be beneficial for those striving to understand and further develop a Culture of Care. Greenhough and Roe interviewed several animal technicians in UK universities to ascertain and describe the behavioural characteristics and challenges of these staff who often 'bear the burden of care'.[6] However, this also gives limited practical guidance and focuses on direct care of animals, which is only one aspect of Culture of Care. The focus of the EFPIA work relates to the values and behaviours of organizations and individuals as our view is that providing a structured framework that can support staff in a positive culture will lead to better outcomes for animals.

As scientific knowledge and our understanding of animal welfare are constantly evolving, so are societal concerns regarding the use of animals for scientific purposes. Therefore, it is essential to challenge 'we have always done things this way' to improve animal housing, care and procedures and reduce any negative impact they can have on welfare.

EFPIA RAW group considerations on what Culture of Care means and how this might be assessed

The EFPIA RAW group members have been reflecting on the concept of a Culture of Care and how it is understood and applied across research institutions and companies in Europe. The phrase 'Culture of Care' is used in different contexts but rarely with any defined indicators of what it might look like in practice. The EFPIA RAW group reflection process was initially facilitated by a survey of 16 questions (Appendix 1). If the concept of Culture of Care is new within your organization, we recommend the survey questions (or modified set of questions that could also include questions relating to outcomes and impacts for animals) as a good way to initiate a discussion about what Culture of Care means to your staff.[7] In our survey respondents were asked from their personal view of defining a Culture of Care. Appendix 2 illustrates a selection of the responses.

Following on from the survey, EFPIA RAW hosted a workshop on Culture of Care in February 2017. A summary of the workshop is provided in Appendix 3. The key conclusion from the workshop was the need for EFPIA RAW to develop a framework to help organizations across Europe move towards a greater understanding of what a Culture of Care might look like in practice. The framework that has been developed is intended to facilitate continuous improvement by highlighting indicators of good practice. It is not intended to act as a tick-box exercise and should be used within the context and constraints of an individual organization. The framework has been developed with the commercial sector in mind but many of the principles and practices can be applied in any user establishment. Any Culture of Care is dynamic and continuously evolving and organizations that have an established Culture of Care should consider how they can enhance and develop their existing culture.

Culture of Care framework

The EFPIA RAW group considered how best to develop practical support for companies to assess their own Culture of Care and concluded a simple framework with several categories and indicators of good practice would be effective. Within each category there are also potential challenges described with possible solutions outlined.

The framework has been split into five categories that support the top-down and bottom-up approaches necessary for a good Culture of Care. The five categories start with the values of the company as this is critical in ensuring a Culture of Care permeates across the whole organization. The remaining four categories are strategic approaches at the establishment level, implementation structures, staff support, and animal care and procedures.

Company values

When developing a company policy that outlines the approach to responsible animal research and values animal welfare and care as a priority, including a statement around supporting openness in relation to animal research activities both internally and externally is essential. The approach extends to the breeding and supply of animals and to animal studies conducted by third parties on behalf of the company. The actions of the company are in line with the policy.

Table 1. Company values: Indicators of good practice.

Company-level policy	The company gives details of its commitment to responsible animal use, the 3Rs and animal welfare and has a formal public statement on openness. There is evidence of this commitment in an established framework with stated values and strategic priorities, including the key areas of focus and the resources required to deliver on commitments. Progress, in terms of outcomes and caring practices, is reported annually, actively recognized and built on.
	Staff who care for animals are clearly valued. Their needs and concerns are recognized and championed at a senior-management level. Animal care is highlighted as an area of importance in company statements.
	Senior leaders act as role models for values that recognize and support caring practices.
	Company policies are actively lived and company activities do not undermine these statements, for example, the company expects to work with third parties who hold similar values.
	The third-party collaborations are reviewed by the company and sites visited as required to provide assurance of alignment with company values.
Accountability and dissemination	The policy is owned at a senior-management level, has periodic review dates and is disseminated to employees through global processes such as induction and training and can be accessed easily through an internal website.
Celebrating 3Rs and care excellence	Formal award processes to recognize achievement are in place, for example through company awards that include categories for Culture of Care, openness and the 3Rs. Senior management-level endorsement underpins the importance of the 3Rs and Culture of Care.
Openness	The company is committed to being clear about why and how it uses animals in research. It is open about the limitations and discusses harm when considering the harm-benefit balance.
	The company publishes information on its animal use on its website. This may include, for example, information on its therapy areas, images from its facilities, numbers of animals used and case studies of its animal research and 3R activities.
	Individuals from the company may speak at public or media events about the company's involvement with and approach to animal research.

3Rs: Replacement, Reduction, Refinement.

Multinational organizations incorporate a wide range of cultures and values that may differ in their views of human-animal relationships. They may also differ in understanding good animal welfare, the relationship between improved welfare and science output, and the willingness or ability to devote resources and budget to animal welfare and the 3Rs. This can be addressed by having a global oversight or governance group within the company for managing company strategy and policies on animal use including developing global values such as supporting caring attitudes in animal research. For example, the global group could agree a set of 'minimum expectations' aligned with the organization's values that can be applied in all regions regardless of laws or culture; for example, in addition to complying with local laws and regulations, it may be a requirement that internal animal care and use programmes follow the principles of the Guide for the Care and Use of Laboratory Animals 8th Edition, Institute for Laboratory Animal Research[8] or the Directive.[1] Making the expectations 'outcomes' based means they can be achieved in different ways in different cultures, for example using a performance approach promoted through organizations such as the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC).[9]

Animal research can be an emotive topic and this can engender caution and concerns about openness, especially in organizations where many staff members are not connected to animal work. The global group may raise awareness and educate leaders and staff on the benefits of openness. Signing up to activities such as the 'Concordat on Openness'[10] (or European equivalent) can help demonstrate that being open about why and how animals are used in research is a positive thing. There may need to be an acceptance that greater openness, for example engaging with the media, may not be achievable in some corporate environments. It must be considered that animal work within large companies is a relatively small part of the overall company activities and thus is unlikely to have a prominent profile in company communications. In addition, there are limitations in that speaking to the media is usually confined to one or two individuals with clear understanding of company messaging in this area. The qualities of a media spokesperson may include:

- knowledge about the regulations, the need for animals in research, the 3Rs and the nuances of animal care and welfare;
- empathy for public concerns about animal wellbeing, be able to communicate the emotional context of this work; and
- ability to tailor their communications to the context and audience appropriately.

Strategic approach – establishment level

The local AWB and other oversight bodies in collaboration with senior management should support a Culture of Care and empower staff working with animals. In this context the person responsible for ensuring compliance with the provisions of the Directive (e.g. Named Person Responsible for Compliance in the UK) has an important role as a senior manager to be visible in promoting a Culture of Care or in nominating another senior manager to do this. It is expected that all persons responsible for ensuring compliance with the provisions of the Directive and the person or persons referred to in Article 24(1) and in Article 25 (Named People) have a critical role in developing and supporting staff and a Culture of Care and are empowered to do so.

Care can be seen to have intangible qualities that can be unrecognized, overlooked and considered low priority at senior management levels. The AWB has a role in preventing this, for example, one approach might be to articulate that care and welfare underpin scientific excellence and that good care supports staff wellbeing. Buy-in at senior level can be supported by articulating with examples that good care reduces risks around welfare compliance.

In a global organization, the establishment vision should ideally align with the company values to support leadership buy-in and help staff feel aligned with the company's values, for example some global organizations may have values aligned to the staff and the company being a good or great place to work. An establishment vision on Culture of Care could be seen to tie into this type of value for the staff working with animals.

Working across management lines with different priorities can be a challenge. It requires active engagement and management at all leadership levels. Effective teamwork and two-way support to and from senior leadership with a clearly articulated visions can help. A Culture of Care is a way of working and should be emphasized in all discussions, rather than treated as a separate standalone 'activity'.

Providing facility tours in a large organization may require significant resources and the provision of virtual tours (e.g. narrated videos) may provide a different approach to minimize any resource constraints.

Implementation structures

The establishment has clear structures that support and facilitate a Culture of Care.

The assessment of individual attitudes to animals and animal care can be difficult during the recruitment process. Care needs to be taken to ensure that potential new recruits are caring and empathetic with a good

Table 2. Strategic approach – Establishment level: Indicators of good practice.

Local engagement at senior level	The AWB and the person responsible for ensuring compliance with the provisions of the Directive are visible and demonstrate a commitment to delivering a Culture of Care at the establishment, for example by visiting the facility and staff, hosting local events, having members of the AWB listed on an internal website or on posters.
	Other named people (e.g. designated veterinarian, animal welfare officer) are supported in their endeavours to promote a Culture of Care.
Establishment vision	The establishment has developed its own vision of Culture of Care involving staff and the AWB. This is articulated to staff and local leadership (for example, through a 'Culture of Care' pledge (Appendix 4) or AWB statement). The vision is actively promoted, for example through the AWB, facility and research managers. Including the vision in induction for new staff and visitors is a useful structural element. The vision can be used as a tool to recognize and reward good practice and to support openness. The vision, as it relates to working practices, is regularly evaluated to check it remains relevant and put into practice.
AWB scope	For example, the AWB considers all animal use in scientific procedures including animal use outside that governed by the legislation, for example use of animals in non-regulated procedures, use of invertebrates.
AWB resource	The AWB have adequate resource to deliver all the functions of an AWB and to support and promote Culture of Care. For example, this might include a budget to support continuing education of AWB members including lay or external members to be able to invite external speakers or fund CPD sessions relevant to the functions of the AWB and to sponsor events (e.g. 3Rs) and provide recognition awards. It might also include dedicated literature search resources to help applicants and the AWB address replacement options.
	The person responsible for ensuring compliance with the provisions of the Directive acts as a sponsor to ensure the resource.
AWB membership	A diverse membership is encouraged to enable different ethical perspectives to be considered. It is strongly recommended that animal care and technical staff should be members of the AWB as this enables their voices to be heard. This is an important factor in a good Culture of Care where animal care and technical staff often carry the burden of care.
	Lay and independent members offer diverse views and enabling their views to be aired can provide constructive challenge including questioning accepted practice or the establishments historical status quo. An independent chair can provide additional perspective and neutrality.
AWB annual goals	The AWB sets goals. This demonstrates a proactive approach to continuous improvement and improving standards. The goals might, for example, include sponsoring a sub-group to consider a Culture of Care alongside other goals such as 3Rs, compliance reporting and protocol review. The goals are reviewed by the AWB throughout the year.
Staff involvement	The local culture empowers staff to have a 'bottom-up' approach to care. The AWB and local leadership promote collaboration and recognition across teams especially between animal technicians and scientists.
Open AWB	AWB meetings are open to all staff, not just those working with animals. Dates of meetings and agendas are made available to staff at the establishment. Minutes are shared and may be published on internal web areas.
	Allowing a wide number of staff to attend supports a forum for discussing ethical, scientific and welfare topics.
AWB sponsored activities	Talks on animal research and facility tours are available and offered openly for any staff within the company, students and visitors from organizations external to the company.
	Open days may be organized for family and friends and other members of the public.
	Development of novel methods for accessing the facilities, for example virtual tours.
AWB communication processes	The establishment has developed communication methods that help support a Culture of Care, for example a local newsletter or internal website. There are regular communications from the AWB including meeting updates, newsletters, legislative information.
Outreach	Presentations on animal research may be given at local schools and colleges or other groups on request through company outreach groups.

AWB: animal welfare board; CPD: continuous professional development.

Table 3. Implementation structures: Indicators of good practice.

Recruitment	The recruitment process for staff working with animals involves an assessment of an individual's attitudes to animals and animal care and welfare as well as technical skills and knowledge.
Induction	The company's approach to the use of animals in research is addressed in all staff inductions. New starters are closely mentored or buddied to provide support and to provide an ongoing assessment of their attitudes to animal care.
	Staff beginning work in the animal facility are introduced to the Culture of Care vision and the expected conduct in that environment is outlined.
Roles, responsibilities and accountability	Roles and responsibilities are clear and visible to all those involved in animal research within the establishment. For example, posters or organograms on display outlining the members of AWB, management of the animal care and use programme and named people. Senior leaders are role models for oversight and Culture of Care.
	All staff are supported by their team and others to take personal accountability for their work, including when things do not go as planned.
Empowerment	Staff are empowered for the level of responsibility as defined in their job descriptions. There is a clear understanding of which decisions would require more senior input.
Local standards	The establishment has developed its own vision of a Culture of Care involving staff. As such this is visibly demonstrated through local standards, for example including the vision in the induction for new staff and through other standards that demonstrate care and commitment, for example euthanasia policy, enrichment, rehoming and staff compassion.
Training and assessment of competence	The establishment has developed training methods that assess knowledge, skills and behaviours allowing elements of attitude towards animal care and 3Rs to be assessed. For example, assessors can observe how animals are handled during the assessment and ask staff how they consider the 3Rs in the procedure they are performing. Initial training plans and reassessment timeframes are defined in local policy.
	This assessment process is clear to staff and is used for all new training and reassessment. Records of training and reassessment are kept by individual staff and the establishment has a centralized overview.
CPD	All staff working with animals are expected to take part in CPD and have time built into their work schedules for CPD. CPD may be broad, for example encompassing science, technology, welfare and wellbeing.
	CPD records are kept and there is oversight by local management.
	The establishment actively provides resources (e.g. literature reviews, webinars, invited speakers, local poster events) for CPD.
Shared goals	Managers work across teams to promote that the scientific and animal technical/care teams to have some shared goals. These might relate to advancing new technology or 3R initiatives and help build an integrated in vivo community.
Learning and continuous improvement culture	The organization has a learning culture and processes that support open reporting of near misses and incidents as well as reporting positive observations.
	Mechanisms for sharing good practice and learnings across different parts of the organizations are established. Issues are shared widely to avoid repetition in other areas and to maximize benefits for animal and staff welfare.
Mechanisms for raising concerns	Staff are supported to raise concerns openly in the spirit of learning, continuous improvement and no blame culture.
	The establishment has independent and confidential mechanisms for raising concerns. All staff are made aware of how to access this. Staff are made aware that anyone who reports concerns in good faith will be supported by management and will not be subject to retaliation. Staff feel comfortable enough to raise concerns.
Processes for recognizing good practice	The establishment has a structured or formal process for recognizing, acknowledging and rewarding good practice and supporting openness, for example recognition and reward is a standing agenda item for every AWB meeting. Departments using animals have mechanisms for recognition and appropriate rewards.
	All staff are made aware of how to recognize colleagues and nominate them for awards.

(continued)

Table 3. Continued.

Disseminating good practice	The establishment has mechanisms for ensuring local good practice (e.g. refinement of procedures) is evaluated, disseminated and shared, for example encouraging and supporting visits to other sites, presentations at local events, posters and presentations at conferences, and publications.

AWB: animal welfare board; 3Rs: Replacement, Reduction, Refinement; CPD: continuous professional development.

attitude towards animals and animal care and welfare and understand the rationale for the use of animals in research. Expert training of interviewers to ask appropriate questions and to enable identification of 'red flags' is beneficial. It should also be understood that attitudes based on care and empathy are reliant on a supportive organizational culture that nurtures them and that recruitment practices alone cannot provide 'caring attitudes'.

Changes to established working practices in the light of new methods can challenge staff and, if handled badly, can imply criticism of existing approaches. Expertise in change management can be useful to ensure everyone understands and embraces new ways of working.

Although the company's approach to using animals in research may not be considered as important or relevant for non-animal staff, it is essential there are processes that enable all staff to have an awareness of and feel comfortable with the company's approach to animal care and welfare and its standards in relation to animal research. Staff can be the best advocates for a company's approach to animal care and their advocacy can support the positive reputation of the company.

Staff can be uncomfortable in raising awareness when something does not go as planned or could be improved. Encouraging staff to fully own their work can be championed, so that successes and errors become shared. Developing a culture of openness and learning requires time and commitment to develop trust and this trust is essential. Senior managers are ideally placed to promote a culture of learning from mistakes rather than looking for blame. In addition, the AWB is ideally placed to support open and transparent processes that enable learning to be shared from things that go well and things that do not. This will maximize the derived benefits and support animal and staff welfare. This could include mechanisms for visibility of small as well as significant successes, for example regular AWB rewards that encourage and promote caring behaviour and thank staff for small improvements in care and welfare.

Good training and assessment processes that include assessments of skill, knowledge and behaviour take time to develop and embed, especially if there are many procedures to be assessed/reassessed. This time

investment can be promoted through the fact that staff feel more invested and these approaches support staff if compliance issues arise.

Collation of items for newsletters and continuous professional development (CPD) opportunities requires resources, time and money. These are ideal tasks to be assigned to a member of the AWB or the animal facility manager. There are often many opportunities to find speakers internally for CPD thus reducing costs.

Staff support

The establishment has local leadership that supports and develops mechanisms demonstrating care and commitment to staff who work with and care for animals.

Conducting procedures on and caring for animals needs to be recognized as a competence and expertise that is a prerequisite for good science. This will help provide the rationale to support membership of animal technology societies and individual development planning in the same way scientists are expected to be members of scientific societies and have individual development plans.

Opportunities for professional development require well-developed training programmes and the identification of relevant skills by managers.

Local management and/or the AWB have a role in promoting two-way interactions between scientists and animal technicians and care staff. This can include ensuring processes are in place before individual studies start where it is expected there would be a discussion and handover between the scientists and animal technician or care staff. The AWB may also request or sponsor scientific presentations that are pitched at an appropriate level for animal technicians to appreciate. Raising awareness of why this is important is critical to the success in outlining the benefits of having engaged animal technicians and care staff to deliver high-quality studies from both a science and welfare perspective. Boden and Hawkins provide good advice for animal care and technical staff on communicating refinements to scientists.[11] The animal technician or care staff role should not be, or be perceived to be, a service that delivers tasks without a full understanding of the goals and what might be expected.

Table 4. Staff support: Indicators of good practice.

Professional attitude	All staff working with animals are encouraged to recognize that their work is a profession and they are supported to be members of animal technology and welfare societies. All staff working in and with the animal facility are expected to maintain professional levels of conduct and to speak to, and about, each other in an appropriate, respectful and courteous way that acknowledges and values a diversity of views and skillsets.
Training and CPD	All staff working with animals have individual development plans and are supported in these. The individual development plans can be used to support future aspirations, for example someone who aspires to become a manager may be supported to attend leadership courses or informally supervise a small number of staff. Other examples might include supporting staff to attend specific workshops, to speak at conferences or to get involved with openness activities such as speaking to schools/students or providing tours of the animal facility.
Communication processes between scientists and animal staff	Two-way communication activities between scientists and animal technicians/care staff are supported and actively promoted. Pre-study feedback meetings allow all contributing to the study to understand the study objectives and ask questions and share expertise. The animal facility's technical staff can raise any issues that may relate to the study procedures or conduct before the study begins. This approach engages animal facility technical staff in their activities and gives them a further opportunity to understand the purpose of what they are doing. In addition, this two-way dialogue between animal facility technical staff and scientists provides a mechanism to improve scientific quality and address welfare concerns before the study starts. Post-study meetings provide an opportunity for the scientists to share outcomes and for the animal facility technical staff to fully understand the role they and the animals played. In addition, it provides an opportunity for both parties to share learnings and improvements (e.g. 3Rs). Presentations on new scientific models, joint presentations on study outcomes with scientists and animal technical/care staff presenting. Technicians are encouraged to present to the AWB and to their wider scientific community on relevant welfare innovations or on husbandry practices to encourage better experimental design and mutual appreciation of animal welfare practices
Valued staff	Staff are recognized for caring and empathetic attitudes in their daily tasks and putting the animal at the forefront of their work, for example through behaviours such as considering animals as individuals rather than a collective, by considering the animals needs and welfare first in each task conducted and being open and flexible to continuously improve the way things are done, being diligent and observant. Recognition might be a formal 'thank you' from the AWB, the person responsible for ensuring compliance with the provisions of the directive, or in the form of a small reward, for example a coffee voucher or gift voucher. This type of recognition helps re-enforce positive behaviours and attitudes. Staff are encouraged to talk about the work or attitude for which they have been recognized to spread good practice.
Emotional support	There are systems and resources in place (e.g. independent counselling) for staff who require emotional support, for example those humanely killing animals. Staff are made aware of how to access these systems and resources and are strongly encouraged to use them. Staff are compassionate to colleagues and openly recognize and celebrate achievements across teams.
Feedback	The establishment has mechanisms that support two-way feedback. Staff are listened to and feedback is addressed or followed up in a consistent manner. Anonymous staff surveys generally indicate a positive workplace where staff feel valued, recognized and supported with small areas for improvement highlighted. Staff are open and have usually highlighted these without the need for anonymous surveys.
Supporting change	Understanding of the impact of change on staff and providing support is critical to success.

AWB: animal welfare board; 3Rs: Replacement, Reduction, Refinement; CPD: continuous professional development.

Table 5. Animal care and procedures: Indicators of good practice.

Supply	Animal supply is considered so that factors such as transport conditions, routes and transit times are understood and refined in the context of animal welfare. There are mechanisms for two-way feedback between the company and the suppliers.
Care	Animal care is valued as an integral part of in vivo science. Care staff contribute and are respected for their views. Caring attitudes are evident, for example through the way animals are handled and treated.
Housing, husbandry and enrichment	Housing, husbandry and enrichment provisions are continually assessed in line with current literature or in-house observations and adapted when appropriate. The AWB supports an active programme of review.
Procedures	Procedures are implemented using recommended good practice, for example single needle use, non-aversive methods of mouse handling and are reviewed in line with emerging literature or knowledge, for example surgical procedures, new technologies for imaging and tumour assessment. Staff are supported to be involved with initiatives that are assessing new technologies or approaches.
Severity	The severity of procedures is regularly reviewed to consider any new opportunities to minimise severity. Procedural, contingent and cumulative suffering are all considered as harms to the animals used in an interconnected way rather than individually.
Refinement	Refinement provisions are frequently assessed in line with current literature or in-house observations and adapted when appropriate. The AWB supports an active refinement programme. The AWB may ask for an annual report of refinements made within the establishment. Methods of humane killing are considered and discussed within the establishment.
Experimental design	The principles of good experimental design are rigorously applied to each study using animals. Statistical expertise or resources are used where appropriate. This includes principles such as power analysis, and opportunities for reducing bias such as randomization and blinding. The AWB provides oversight for experimental design principles. Scientific review of studies by those not directly involved in the study can be beneficial as can the input of a statistician.

AWB: animal welfare board.

Animal care and procedures

The establishment has processes that support continuous improvement in the 3Rs and that when animals are used, there is appropriate experimental design and refinement in care and welfare practices.

Understanding of animals' needs and the impact of housing, husbandry and procedures continue to evolve. There is often a concern of the potential impact of enrichment on scientific outcomes and therefore it is important that there is a collaborative approach to assessing new approaches. The evidence base may focus on animal welfare alone and the impact on science and data quality is slower to gather. A good example illustrating this is the work of Hurst on alternative handling methods in mice published in 2010,[12] additional papers on the impact on science have started to be available[13] and training resources available through the UK National Centre for Replacement, Refinement and Reduction of Animals in Research (NC3Rs) website[14] and as the evidence base has grown so has implementation. The AWB has an important role to act as a sponsor of new initiatives supporting implementation and outcomes.

Changes to methods and procedures are more likely to succeed when they have a compelling evidence base and can demonstrate a clear animal welfare benefit, particularly as significant changes may involve increased operating costs either in terms of equipment or resource. However, there are examples of methods that even without an evidence base cause minimal harm to animals and should be adopted (e.g. single needle use)[15] unless there is a scientific rationale for a different approach. It is beneficial to manage change by, for example, spending time introducing the rationale for any changes and related benefits before full-scale adoption; the use of pilot activities and 'champions' can be helpful in overcoming resistance. The designated person responsible for animal care and welfare and the designated veterinarian are likely to play a key role in implementing changes. Collaboration with other establishments that have already made a change may also clarify the benefits and inform any training required. Staff are encouraged to share changes by presenting either at internal meetings or at external

laboratory animal events. Assigning experienced staff as mentors will support this activity.

Statistical support is not always accessible; however, there are several key resources that support good experimental design and reporting that AWB members should be aware of.[16,17,18]

Conclusion

A Culture of Care is an important factor in how animal care and use programmes operate considering both the staff and the animals used. Despite its importance and the available guidance on high-level principles underpinning Culture of Care, the concept remains somewhat subjective and has a different understanding across European countries. The EFPIA RAW framework has been developed by considering good practice indicators that can be applied objectively in European companies operating across a variety of different cultural backgrounds. An example of how the framework might be used comes from AstraZeneca, which has five animal facilities across its global organization. Each facility has used the framework to assess their own Culture of Care and to identify improvement areas. At sites outside Europe terminology was defined, for example, the Institutional Animal Care and Use Committee (IACUC) instead of AWB and attending veterinarian instead of named veterinarian. The chief veterinary officer has completed the assessment against the 'company values' part of the framework. Through global discussions these assessments will be reviewed to share good practice across the five animal facilities and develop global goals and resources where there are common themes for improvement.

Although the framework focusses on human-centric elements, future work in this area could assess a correlation between an improved Culture of Care and animal-centric indicators (e.g. staff-animal ratios, time allocated for animal checking, mortality rates, practice with respect to asepsis and post-operative analgesia).

The AWB has a key role in sponsoring or promoting many of the good practices and processes within an establishment. Although developed with the commercial sector in mind, several of the good practice indicators can be applied more widely.

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Supplemental Material

Appendices 1-4 are available online with this article, https://journals.sagepub.com/doi/full/10.1177/0023677219887998

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Résumé

Les membres du Groupe de recherche et de bien-être des animaux (RAW) de la Fédération européenne des associations et industries pharmaceutiques (EFPIA) ont réfléchi au concept de culture de soins relativement aux soins prodigués aux animaux et à leur utilisation ainsi qu'aux différences relatives à son interprétation et à son application au sein des laboratoires pharmaceutiques européens. Le terme «culture de soins» est utilisé dans différentes régions et organisations mais rarement avec des indicateurs définis pour soutenir les pratiques de travail.

Le groupe RAW de l'EFPIA a développé un cadre de travail pour aider les organisations à identifier les lacunes ou domaines éventuels d'amélioration afin de soutenir une culture de soins positive.

Le cadre de travail est un outil qui identifie cinq domaines de culture des soins dans lesquels se concentrer: valeurs de la société; approche stratégique au niveau de l'établissement; structures de mise en œuvre; soutien au personnel: procédures et soins aux animaux. Le cadre est prévu comme une aide à l'amélioration continue, et met en lumière les domaines dans lesquels des indicateurs de bonnes pratiques sont présents. Nous nous attendons à ce qu'il fournisse des points de réflexion et des idées à ceux qui cherchent à mettre en œuvre une culture de soins d'une manière structurée, tout en facilitant une approche professionnelle et stratégique. Pour empêcher de soutenir un exercice consistant uniquement à «cocher des cases», le cadre ne doit pas être utilisé comme outil de vérification, mais plutôt comme un point de départ afin de prendre en compte et de discuter de la manière dont les soins se manifestent au sein du contexte et des contraintes des établissements individuels.

Abstract

Die Mitglieder der Gruppe Research and Animal Welfare (RAW) der European Federation of Pharmaceutical Industries and Associations (EFPIA) beschäftigten sich mit dem Konzept einer ̈Culture of Care ̈ (Pflegekultur) in Bezug auf Tierpflege und-verwendung und zu Unterschieden in Verständnis und Anwendung dieses Konzepts in den europäischen Pharmaunternehmen. Der Begriff Pflegekultur wird in verschiedenen Regionen und Organisationen benutzt, jedoch selten mit klar für eine Unterstützung der praktischen Arbeit definierten Indikatoren.

Die RAW-Gruppe hat ein Framework entwickelt, das Unternehmen dabei unterstützen soll, Defizite oder Verbesserungspotenzial zur Unterstützung einer positiven Pflegekultur zu identifizieren.

Der Rahmen ist ein Instrument zur Identifizierung von fünf Schwerpunkten für Pflegekultur: Unternehmenswerte, strategischer Ansatz auf Ebene der Einrichtung, Umsetzungsstrukturen, Mitarbeiterunterstützung, Tierpflege und-verfahren. Der Rahmen ist als Hilfe für die kontinuierliche Verbesserung gedacht und zeigt auf, wo Indikatoren für bewährte Verfahren vorhanden sind. Wir gehen davon aus, dass er Anhaltspunkte für Überlegungen und Ideen für jene liefert, die sich um eine strukturierte Umsetzung der Pflegekultur bemühen, und gleichzeitig einen professionellen und strategischen Ansatz ermöglicht. Damit sich der Rahmen nicht lediglich als Übung zum ̈Abhaken ̈ von Aufgaben erweist, darf er nicht als Audit-Tool Verwendung finden, sondern muss als Grundlage für Überlegungen und Diskussionen darüber dienen, wie sich Tierpflege im Kontext und unter Berücksichtigung der Zwänge in den einzelnen Einrichtungen darstellt.

Resumen

Los miembros del Grupo de Investigación y Bienestar Animal (RAW) de la Federación Europea de Asociaciones y Sectores Farmacéuticos (EPFIA) reflexionaron sobre el concepto de una Cultura de cuidado en relación al cuidado y el uso de animales así como sobre las diferencias que existen en su comprensión y aplicación en compañías farmacéuticas europeas. El término «Cultura de cuidado» se utiliza en distintas regiones y organizaciones pero raramente con indicadores bien definidos para respaldar la práctica laboral.

El grupo RAW de la EFPIA ha creado un marco para ayudar a las organizaciones a identificar brechas o posibles áreas de mejora a fin de fomentar una Cultura de cuidado positivo.

El marco es una herramienta que identifica cinco focos para la Cultura de cuidado: valores empresariales; método estratégico a nivel de establecimiento; estructuras de implementación; apoyo al personal; cuidado animal y procedimientos. El marco está pensado como una ayuda para la mejora continua y marca cualquier indicador de buena práctica que haya presente. Esperamos que facilite puntos de reflexión e ideas para los profesionales que deseen implementar una Cultura de cuidado de forma estructurada, facilitando a su vez un método profesional y estratégico. Para evitar una práctica mecanizada, el marco no debe utilizarse como una herramienta de auditoría sino como un punto de inicio para considerar y debatir el modo en que el cuidado se presenta en el contexto y en las restricciones de los establecimientos individuales.