



VETBIONET

Veterinary Biocontained facility Network for excellence in animal infectiology research and experimentation

Deliverable D4.1
Open Science and Stakeholder Engagement Strategy Report

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1. Summary

Objectives:

The aim of this deliverable is to set out a strategy document that will support the embedding of stakeholder engagement and open science approaches. By defining and encouraging reflection on broader principles it is hoped that the document will support the development of best practice approaches within VetBioNet. This report (*Deliverable D4.1 Open Science and Stakeholder Engagement Strategy Report*) represents the first version of the Transparency and Stakeholder Engagement Strategy (TSES) and will inform the work of the Network going forward, however it is dynamic document for the project and as such the TSES will be reviewed and revised (with possible revised submissions of the document) throughout the life of VetBioNet.

Rationale:

In order to develop the strategy, a documentary analysis was conducted, from this, relevant underpinning principles and European Commission (EC) policy approaches were identified. Good science governance principles have been defined by the EC as (i) openness, communicating accessibly with the public; (ii) participation by citizens as much as possible in all policy formation; (iii) accountability clearly apportioned among EU institutions; (iv) effectiveness in achieving goals and objectives; and (v) coherence among institutions and policies.

As part of the VetBioNet approach to embed ethical reflexivity, which is informed by the good governance and EC Responsible Research and Innovation (RRI) principles, it is important that approaches to stakeholder engagement and open science through transparency are operationalised. These policies and principles of engagement and transparency are first discussed in concept and then in relation to animal research and finally are shown to inform the identification of the applicable issues for VetBioNet going forward. This strategy will be operationalized through the work of the network, however, a number of areas have initially been identified, such as approaches to (i) data protection and openness, (ii) publication, (iii) stakeholder engagement rationales, and (iv) use of engagement tools.

Team involved:

This report is authored by the University of Nottingham team (UNOTT).

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2. Objective of the Transparency and Stakeholder Engagement Strategy

The Transparency and Stakeholder Engagement Strategy (TSES) document (*Deliverable D4.1 Open Science and Stakeholder Engagement Strategy Report*) is produced to inform the overall work of the Veterinary Biocontained facility Network for excellence in animal infectiology research and experimentation (VetBioNet), specifically relating to how the consortium reflects and works to embed a reflective process in the consortium's activities, particularly around stakeholder engagement, transparency and reflexivity in experimental design.

This strategy document firstly sets out some of the core concepts, policies and EU frameworks that underpin and justify the need to consider approaches to stakeholder engagement and transparency principles. This is done through discussion of best practice principles for stakeholder engagement and transparency in line with current EU principles on open science and responsible innovation. Principles embedded in specific animal research related policies, for example the Basel Declaration are then discussed. The strategy is therefore structured around three elements: Openness, Responsible Research and Innovation (RRI) and Engagement.

This document outlines the policy and principles of Engagement and RRI in Europe. This is followed an examinwhat these principles mean for the VetBioNet Consortium are considered, specifically in terms of openness, engagement and the value of this work to society. Finally, this TSES is linked to several of activities that will take place during the project and the value of these activities for this project and for the sustainability of future work is highlighted.

3. Inclusiveness in EU research and policy making

In its efforts to bring research and innovation closer to society, the EC has called for a more inclusive governance of research and innovation. This has been associated with a rise in the inclusion of those outside the research process itself, with a focus on bringing in new voices which previously have not been directly involved or consulted in how research should be shaped and delivered (Stilgoe et al. 2014).

Before discussing the principles that can guide the work of VetBioNet it is important to explore the EC's vision of the underpinning policies and principles that guide good practice in the engagement of stakeholders in scientific research and the ethical approaches that should inform sound experimental design and innovation practices. The following section briefly discusses the relevance of stakeholder involvement in the context of European research policies.

4. European Research Area

The core of the EC's agenda for proceeding towards a European Research Area (ERA) is the necessity and will to address societal needs, specifically to develop approaches for tackling the grand challenges and also to foster a global perspective in the research process. The ERA is structured to allow all actors, both public and private, to operate together, in alliance and to cooperate to achieve a common global goal that responds to all interests equally (European Commission, 2010). Science is considered to be important to support innovation, technological development and socio-economic changes. The conception of science as a social institution (Ozolina et al., 2009: 5) that produces action-oriented knowledge, ascribes a specific role to this domain in the shaping of societally relevant future developments. In recent years this has led to debates on topics such as global governance, ethical assessment and the emergence of the notion of 'ethical dumping', as well as responsible research and innovation (RRI) have been emerging in recent years. Global governance is considered the core guiding principle of stakeholder involvement in research: global can mean comprehensive, referring to all areas of science, but can also mean going beyond national boundaries. A critical step in allowing for successful governance of a scientific field in today's inter-connected world is to involving key stakeholders on a global basis in the assessment and management of risks, uncertainties, the definition of societal needs and ethical issues, and control over research-funding.

5. Scientific Governance

Science governance is built on relationships such as those between nations and transnational organisations; between state and civil society and those between different categories of society and the mediation of power between policy-makers and scientists (Ozolina et al., 2009: 12). Following a white paper on European governance, the following good science governance principles were defined and it was proposed these should be enacted in science programmes (Ozolina et al., 2009:9):

- openness, communicating accessibly with the public;
- participation by citizens as much as possible in all policy formation;
- accountability clearly apportioned among EU institutions;
- effectiveness in achieving goals and objectives;
- coherence among institutions and policies.

Moreover, it is claimed that the application of these five principles promotes proportionality and subsidiarity, which are also foundational to European Union governance. In situations where responsibilities are distributed equally among all the actors involved in the process of innovation, both upstream and downstream, this represents a model of responsible governance. This concept of responsible governance has developed over several of years and is now an important concept in EU research programmes. This is further explored below and finally discussed in the context of VetBioNet.

6. Responsible Research and Innovation in Europe: Policy and Principles

Responsible Research and Innovation (RRI) is now a core agenda in European research policies. This section sets out the history and current status of RRI in Europe as well as describing the role of stakeholder engagement and transparency within this dialogue.

In 2001 the Science and Society Action Plan was launched with the aim of improving the connection between science and European Citizens. In 2007, under the 7th Framework programme for Research and Technological development (FP7), Science in Society (SiS) defined their main objective to 'foster public engagement and a two-way dialogue between science and civil society' (EC Responsible Research and Innovation, 2012). The development of a framework for RRI has been the focus of SiS since 2010, where

Responsible research and innovation means that societal actors work together during the whole research and innovation process in order to better align both the process and its outcomes, with the values, needs and expectations of European Society.

(EC Responsible Research and Innovation, 2012)

The RRI agenda appears to have been widely accepted in Europe, indeed, the Rome Declaration on Responsible Research and Innovation in Europe (2014) builds on the earlier 2009 Lund Declaration and the 2013 Vilnius Declaration (which focused particularly on societal challenges and actor partnerships respectively). Importantly, EU citizens' rights have been argued to provide the basis for the principles of responsible research decision making:

Decisions in research and innovation must consider the principles on which the European Union is founded, i.e. the respect of human dignity, freedom, democracy, equality, the rule of law and the respect of human rights, including the rights of persons belonging to minorities (Rome Declaration, 2014)

Accordingly, the current European 2020 Horizon strategy promotes Responsible Research and Innovation using a framework which encompasses six 'keys'; Engagement, Gender Equality, Science Education, Open Access, Ethics and Governance. The principles of stakeholder engagement and transparency, which are part of the VetBioNet strategy, are described and justified by the two of the European Commission's 'keys' as follows:

The first key is engagement of all societal actors – researchers, industry, policy makers and civil society – and their joint participation in the research and innovation process, in accordance with the value of inclusiveness, as reflected in the Charter of Fundamental Rights of the European Union.

In order to be responsible, research and innovation must be both transparent and accessible. Our fourth key is to make open access a reality. This means giving free online access to the results of publicly-funded research (publications and data). This will boost innovation and further increase the use of scientific results by all societal actors.

Six key components of the Horizon 2020 programme can be seen to in some way operationalise the five principles of good science governance as set up by the Commission in the White Paper (Ozolina et al. 2006)

From these overarching concepts and principles, two specific aspects are important for the work of the VetBioNet members, the principles of engagement with wider stakeholders and transparency. To develop greater academic understanding of these concepts the next section will consider these principles and discuss them in terms of how they will apply in the animal research context.

7. Principle of Transparency

As part of the discussions about the guiding principles in science, in particular concepts of openness and accountability, it is not surprising that the notion of trust has emerged as an importance principle. In line with the developing interest in, and acceptance of the RRI agenda in European policy, commentators and researchers interested in areas of scientific controversy and controversial science have identified a contemporary preoccupation with transparency and openness in science and governance (McLeod and Hobson-West, 2016). It is argued that the primary rationale for this recent development relates to reduced public trust in science (McLeod and Hobson-West, 2016). Public mistrust and the critical role of transparency have been related to specific negative societal events for example, the BSE crisis (Philips, 2000).

It is unclear what transparency means in science specifically remains unclear, McLeod and Hobson-West (2016) assert that transparency has no single definition; that it is 'more often invoked than defined' (Hood and Heald, 2006: 3). Furthermore, the optimal degree of openness

in science may be limited because transparency might conflict with other important principles, meaning that the 'degree of openness is context-specific and needs to be traded off against other important social values' (Jasanoff, 2006).

However, the value of transparency is well argued, with this principle being frequently considered to be an enabling tool for engagement (Irwin, 2006; Rowe and Frewer, 2005; Wynne, 2006) or even the co-production of knowledge (Jasanoff, 2004). The principle of transparency is also academically linked to ideals of good governance through policy and regulation (Gonvalves, 2006; Hood and Heald, 2006)

8. Principle of Engagement

The need for wider engagement and inclusion in science has been discussed in earnest since the 1990s as because of a number of public debates surrounding novel biotechnologies and food scandals such as BSE. As such it has been argued that the initial drivers to see greater engagement and interest within scientific institutions to engaging with publics, as with the openness agenda, are rooted in public mistrust. Specifically in the handling of scientific and technological controversies by the state which, it is argued, has fuelled public opposition to technical change (Irwin, 2006). Consequently, there has been notable support for public engagement initiatives around controversial topics (Goven, 2006) and beyond.

A further common strand between the principles of transparency and engagement relates to the deficit model (Stilgoe et al 2014) whereby a lack of trust by the public is considered to result from a misinformed public. This deficit approach to openness and engagement may result in a specific and limited type of public engagement, designed to win the public's support (Felt and Fochler, 2010)

In fact, contemporary approaches to engagement both recognise and promote different degrees and types of stakeholder participation (Cornwall, 2008:271). For example, consultative and participatory approaches (Roberts, 2003), or communication, consultation and participation mechanisms (Rowe and Frewer, 2005). Felt et al (2007) identifies three models of science and society relationships: education, participation, and the co-production of knowledge. It has recently been argued that the reality of engagement is somewhere between these proposed distinct boundaries in approach (Tlili and Dawson, 2010)

Advocates of engagement are also explicit in stating that the purpose of engagement, not just the process, should be considered important (Goven, 2006). For example the three motivations/rationales for promoting engagement with science and technology are suggested (see Appendix 1) to be (i) instrumental, (ii) substantive, and (iii) normative (Marris and Rose, 2010; Pallet, 2010)

With regards to defining stakeholders for engagement, whilst broad and detailed classification of different groups are adopted within specific disciplines (see for example Ross 2003; Brugha and Varvasovsky 2000; Reed et al. 2009) this practice is not widespread. Terms such as stakeholders, the public, citizens, and interested parties are commonly used interchangeably and without specific definition (Ribeiro and Millar, 2015). The loose use of the term stakeholder or using this term and society as synonymous has also been criticised (Ilhen, 2008; Goven, 2006)

In the EU context, stakeholder engagement in science is now considered a critical part of an RRI approach:

Over the last decade, Member States and the European Commission have continuously supported structured participation in issues involving scientific and/or technological dimensions (Felt et al 2007)

Indeed, researchers interested in engagement approaches have again identified the direct link between European sustainability principles, the co-creation of knowledge and societal benefits:

The new H2020 objectives promoting the uptake of RRI, which is intended to build on the longstanding sustainability principles, appears to be encouraging the involvement of a range of representative (e.g. researchers, industry etc.) and public voices in the development of science, technology and innovation so that these can in some form be co-created to ensure wider societal benefit (Ribeiro and Millar, 2015)

Ribeiro and Millar (2015) highlight that H2020's key action of RRI, points to public engagement as being strategic in three main areas:

- *To increase society's scientific literacy and thus its ability to participate in democratic processes involving science and technology developments;*
- *To contribute by including diverse perspectives in research design and results; and*
- *To align research and innovation with societal needs to help overcome a range of societal challenges.*

In the next section, stakeholder engagement in the animal research context is considered more specifically.

9. Transparency and Engagement in Animal Research

It is important to consider these concepts more generally in the context of animal research before reflecting on the implications of the VetBioNet and which activities they support within the Consortium.

10. Engagement in Animal Research

The importance of embedding reflective processes in animal research has been recognised as part of sound experimental design from the time of Russell and Birch's (1959) seminal book on the 3Rs of experimental design. However, the benefits of opening up the reflective process and bringing in new voices through the inclusion of stakeholder and wider public voices has been a recent focus for institutions and funders.

The process of both real-time and upstream engagement can be seen in several forms as:

- Stakeholder and public engagement in funding decisions
- Public or lay person involvement in ethical review
- Stakeholder engagement within the research work

These three levels reflect the way in which existing and new initiatives are attempting to bring in external voices which can help to shape what work is funded, what work is licensed and what work is prioritised and carried out as part of on-going projects.

New initiatives that cover these levels of engagement are often characterized as being driven by all three levels of the rationales for promoting engagement with science and technology (Marris and Rose, 2010). In animal research, motivations may be seen to be instrumental as engagement in itself may lead to greater public trust and less conflict. In terms of substantive motivations these relate to the idea that incorporating lay knowledge can help to frame and shape, for a better outcome, innovation processes by providing a different perspective. For example, within animal research engagement may mean better characterization and understanding of harm-benefit analysis. Finally, the driver related to the normative dimension refers to the notion that there is an ethical requirement to involve publics in science innovation processes, particularly as a significant level of cutting edge science is funded by public money. This is true for animal research, particularly related to areas such as infectious disease.

Some initiatives in the animal research field have been developed which embed the principles of engagement and greater openness; these approaches focus on targeted activities. In the UK the inclusion of lay members as part of the Animal Welfare and Ethics Review Board (AWERB) is required. The inclusion of lay members was intended to facilitate a form of opening up of the assessment of experimentation proposals and introduced a wider perspective that may be seen as extending beyond institutional paradigms. However, whether this occurs in practice is not clear as limited empirical work has been conducted.

Both national and EU research funders have somewhat opened up their review boards with greater inclusion of stakeholders and non-commercial board members. Again, this could be termed opening up and deemed to be a form of engagement, it is unclear if the inclusion of different types of perspectives is needed for projects involving animal work or what is appropriate, as some stakeholders may be too aligned with the working paradigms of the funder and in particular paradigms related to animal use and the application (or lack of application) of the 3Rs.

There have been some initiatives to engage with stakeholder perspectives as research work progresses. This can be achieved through targeted events and activities. Some larger projects create stakeholder platforms that comprise of a range of stakeholder from industry through to NGOs. If these platforms are populated with committed individuals and their time is used effectively then these activities can be informative for both the project team and the researchers.

11. Transparency in Animal Research

There is a body of academic literature that has explored notions of transparency and science policy-making in a range of settings, such as agriculture in the EU (Heard-Laureote, 2007), environmental governance (Gupta, 2008), and fisheries (Wilson, 2009).

Empirical studies on transparency and openness in animal research are limited (McCleod and Hobson-West, 2016). However, early discussions of openness around animal experimentation can be found, for example in 1991 Arluke describes the 'dilemma of information control' practised daily by animal researchers. O'Sullivan (2006) claims that animal advocacy groups assume more transparency will produce greater opposition to animal research, but that is not necessarily supported by the current trend and as such animal researchers claim openness may lead to greater understanding of the value, and hence greater support. There have been challenges from commentators on animal use: O'Sullivan claims animal researchers are 'slow to open the laboratory door' (2006:14).

However, experiences of *in vivo* researchers who were subjected to forms of direct action and forms of harassment and intimidation in the 1980s and early 1990s, specifically in the UK, has affected willingness to be fully open. Some researchers are still mindful of being targeted and this has been deemed to affect the nature and speed of changes in levels of transparency.

With the above reservations amongst researchers noted, animal researchers have been charged with employing a 'selective openness' whereby controlled information is released, equating to an 'enlightenment/deficit model of public communication' (Holmberg and Ideland, 2010: 365) and raising the question of what more openness is expected to achieve? (McCleod and Hobson-West, 2016). Some authors have focused on the dark side to transparency

(Nerlich, 2013), specifically, it has been argued that operationalising transparency can complicate rather than produce trust in science-public relations (Fox, 2007; Jasanoff, 2006; Stathern, 2000). Animal research has been especially criticised for being secretive (Nuffield Council on Bioethics, 2005) and in the UK, organisations critical of animal research have long called for more openness (Monaghan, 2000). However, more recently, organisations involved in animal research also seem to be embracing transparency discourses (Jump, 2014).

Some of the initiatives to encourage openness have come from researchers, institutions, funders and animal charities. These actions have been targeted at areas of research involving specific types of animals, such as non-human primates. However, an international initiative was developed and launched in 2013, the Basel Declaration. This Declaration aims to bring the scientific community together to further advance the implementation of ethical principles and to call for more trust, transparency and communication on the sensitive topic of animal research. There have been a wide range of organizations who have agreed to abide by the Declaration. These signatories, mostly research institutions and researchers in the life sciences sector, declare a public commitment to the 3Rs principles (Replace, Reduce, Refine) i.e., that animal testing in their area of expertise will be planned and carried out with extreme care. In addition, they agree to contribute to providing society with open and transparent information about animal experiments (Further information on the Declaration is available online (at www.basel-declaration.org))

12. Operationalising Transparency and Engagement in VetBioNet

In order to operationalise these principles it is important to identify key tasks and activities for VetBioNet that will be completed over the course of the funded period, however it is also valuable to determine how these principles can be operationalised and useful for the sustainability of the network. A number of the planned activities within the Network (deliverables) will deliver on aspects of the transparency and engagement agenda. Some of these aspects were included during the writing of the proposal, but further operationalization and added value activities may be needed.

It is intended that this document is the first version of the TSES and as such it will inform the work of VetBioNet. However, this strategy is also seen as a 'living document' for the work of the Network. As elements of the work develop in VetBioNet and new literature and tools that relate to transparency and stakeholder engagement strategies emerge, the TSES will be reviewed and revised (with possible revised submissions of the document) and as appropriate these revisions will guide the work of VetBioNet.

In order to operationalise the TSES a four level approach will be used that intends to support the network to: (i) be more aware; (ii) acquire more knowledge; (iii) build skills in applying

approaches and finally; (iv) identify the personal value of embedding a transparency and engagement strategy.

A number of key activities are identified below but as stated above other activities defined in the description of work which are important for the overall application of the TSES and other issues will arise. The VetBioNet activities are discussed under the headings of Transparency and Engagement.

13. VetBioNet and Transparency

There are three areas where VetBioNet can further support the transparency agenda.

(1) Institutional Approaches to Transparency

Across the VetBioNet it is possible to discuss current Institutional policies to transparency and the statements provided. The challenges and expectations of both individual researchers and the institutions themselves can be explored.

Some of these aspects can be mapped out in the initial scoping activity; an analysis of ethical issues in BSL3/BSL3+ animal infectious disease research. This could then become a building block for further discussions under WP4 activities lead by UNOTT.

(2) Open Science

Under WP5, there is a clear dissemination plan lead by EAAP. The work of the partners will be published according to the EC funding conditions, however, further transparency steps can be taken to see how the work can be highlighted through the website and other social-media options, such as Twitter, etc. In addition, the Network will discuss options for making the 'online repository database' tool available, as well as primary data and how that can be done in accordance with EC, institution and data protection requirements.

(3) Greater transparency through good practice training

In order to embed good practice approaches that facilitate transparency, the training component of the WP5 activities will embed training around transparency approaches through the 3Rs Experimental Design Training School (January 2019). The Network will discuss the opportunities to apply the ARRIVE guidelines which supports great transparency in reporting / journal article publication. The WP4 team will also highlight new tools that support greater transparency through the provision of a resource document and news updates (via the newsletter and the website).

14. VetBioNet and Engagement

There are three areas where VetBioNet can further support the engagement agenda with its work:

(1) Building and Evaluating a Stakeholder Network

Through a series of events and activities that span across the WPs (such as WP1 transnational access, WP6 sustainability of the network, WP4 ethics and WP5 dissemination) the VetBioNet members will be interacting with a wide range of stakeholders. In order to facilitate and effectively coordinate these interactions it is important to track these activities across the overall project work. It is also important to evaluate what the stakeholders' perceptions of the nature and value of the interactions in VetBioNet. In terms of exploring these issues, it would be interesting to examine - Do stakeholders' motives for participation match their expectations and the motivations and expectations of the VetBioNet partners?

The 'tracking' of stakeholder interactions is embedded within the activities of WP5. Mindful oversight in WP5 can register these interactions and can also make these stakeholder interactions transparent through information on the website and in the reporting process.

In terms of examining stakeholder expectations, this could be investigated alongside the work in WP5 and possibly be part of the exploration of social dimensions. It will be important to examine; stakeholder perceptions of engagement, including views on the barriers to engagement, whether stakeholder fatigue is an issue as well as the breadth or limits of the stakeholder network that is being built within VetBioNet. This research can also be supported by the stakeholder interviews that will be conducted in WP5.

Both of these tasks may further strengthen the establishment of a sustainable Stakeholder Platform that can provide advice, possible collaborations and critical challenge if needed. This presents a different mechanism to an Advisory Board who have more formal review and reporting responsibilities. Members of a Stakeholder Platform would be able to collaborate directly with VetBioNet partners, in terms of future proposal writing and project work. The establishment of a Stakeholder Platform through the tracking of stakeholder interactions and through understanding stakeholder perceptions could help to sustain the post-VetBioNet long-term vision.

(2) Examine opportunities to involve wider stakeholders in Network and institutional processes

Drawing on the research looking at the rationales for embedding engagement activities within science and innovation programmes, it is notable that both the animal ethical review process and the grant review process involves the evaluations and input of wider stakeholders. As part

of the defined WP5 tasks, the team will examine the work of Ethics Committees in animal experimentation, more formally referred to as Animal Welfare and Ethical Review Bodies (AWERBs) in the UK and Animal Welfare Bodies elsewhere in Europe. It may therefore be possible to consider the roles, strengths and limitations, of including stakeholder voices. The insights from this may be value when considering other opportunities to include stakeholders.

(3) Mapping and reviewing engagement and ethical tools that can facilitate engagement

As well as defining which stakeholders should be engaged and when, a key question is what types of tools can facilitate engagement processes. The work programme of WP4 and WP5 is focused around facilitating ethical reflection and facilitating communication strategies, respectively. Therefore, as part of these activities it would be valuable to map and review which engagement and wider ethical tools may be valuable. Due to the expertise of the UNOTT group it is proposed that WP5 team should review the use of the Ethical Matrix tool (and any recent adaptations of the tool) and how it has been to facilitate engagement and / or reflection related to the use of animal experimental animals. This may then provide a useful tool for VetBioNet.

15. Conclusions

The aim of this strategy is to support the VetBioNet work to embed stakeholder engagement and open science approaches in the research and networking activities. This document sets out and encourages further reflection on principles that are intended to support the development of best practice approaches within VetBioNet. In line with the objective of supporting reflective process this Transparency and Stakeholder Engagement Strategy is a living document for the project and so will be updated as new approaches or issues emerge.

Any comments on this report would be gratefully received please contact Kate Millar (kate.millar@nottingham.ac.uk)

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17. Annexes

Annex 1: Main motivations for involving publics ‘in’ science programmes (modified from Marris and Rose 2010 and Pallet 2012)

Narrative	Description
Instrumental	Public engagement seeks to improve public trust and reduce conflict to smooth the way for emerging technologies. It could also help achieving pre-determined outcomes to serve the interests of more powerful actors
Substantive	Public engagement aims at incorporating lay knowledge to decision-making processes and to improve the suitability of technological developments for their embedding in society
Normative	Public engagement responds to an ethical need or a ‘right’ of publics to be involved in decision-making processes , since science and technology directly affect our lives and are ultimately funded with public money

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