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From Responsible Research and Innovation to responsibility by design

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ABSTRACT

Drawing on more than eight years working to implement Responsible Research and Innovation (RRI) in the Human Brain Project, a large EU-funded research project that brings together neuroscience, computing, social sciences, and the humanities, and one of the largest investments in RRI in one project, this article offers insights on RRI and explores its possible future. We focus on the question of how RRI can have long-lasting impact and persist beyond the time horizon of funded projects. For this purpose, we suggest the concept of ‘responsibility by design’ which is intended to encapsulate the idea of embedding RRI in research and innovation in a way that makes it part of the fabric of the resulting outcomes, in our case, a distributed European Research Infrastructure.

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Introduction

In this article, we reflect on the conceptualisation, research, implementation, and future outlook of Responsible Research and Innovation (RRI) based on work undertaken in one particular project: the EU Future and Emerging Technologies (FET) Flagship Human Brain Project (HBP). We take stock, outline future work and, more importantly, discuss how past, current, and future RRI-related work can remain relevant in the intended legacy initiative – a European Research Infrastructure EBRAINS¹ and we highlight some of the conceptual aspects of the RRI debate that need to be addressed and propose future directions of relevance to the RRI community overall.

The paper seeks to answer two interlinked research questions:

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What can we learn about the strengths and limitations of RRI from the implementation of RRI in a large multidisciplinary research project?

And, following from this:

How can we build on our specific experience to go beyond the current RRI discourse in theory and practice?

We address these questions by reflecting on our experiences as part of the RRI team of the HBP for more than eight years. This article integrates insights from our research, practices, and efforts that we have invested into the HBP. It draws on a broad range of academic interactions.

We have structured the article as follows. First, we provide a brief outline of our view of the RRI discourse and an overview of how we have implemented RRI in our project. Next, we discuss what we have learned from our work and summarise key insights. This is followed by a discussion of the practical implications of our work, and how our experiences and theoretical insights inform our future work. Reflections on our experience lead us to propose building on RRI to develop a concept of responsibility by design to provide specific guidance on how and in what stages to include RRI in a research infrastructure.

The article makes several contributions. By bringing together the work of several different strands of RRI activities in a very large research project, we provide empirical evidence of the strengths and weaknesses of RRI. In particular, we focus on an issue that remains unexplored in the context of RRI, namely RRI's post project legacy. We suggest the concept of responsibility by design as a way to embed RRI into the governance and outcomes of research and innovation activities and to illuminate a dimension that the RRI community needs to address in more detail.

RRI and its implementation in the HBP

This section provides a brief overview of RRI to set the scene for describing how the framework is interpreted in the HBP and how this shapes processes and outcomes in the project.

Responsible research and innovation

Since the start of the discussion of RRI (Von Schomberg 2012; Stilgoe, Owen, and Macnaghten 2013), much conceptual and empirical research has been undertaken to clarify its conceptual basis, feasibility, operationalisation, and practical, social, and political implications. The adoption of RRI frameworks by several research funders (Owen 2014; de Saille 2015) most notably the European Commission (European Commission 2011; European Commission 2012; European Commission 2013), has led to intense reflection on RRI by a community of scholars (Gerber et al. 2020; Shelley-Egan, Gjefsen, and Nydal 2020; Forsberg et al. 2018; Lente, Swierstra, and Joly 2017; von Schomberg and Hankins 2019). However, the discussion of both the definition and the operationalisation of RRI is still open.

It has been suggested that two dominant and distinct but overlapping discourses on RRI exist (Owen and Pansera 2019). Responsible Innovation (RI) -based on dimensions

of anticipation, reflexivity, inclusiveness, and responsiveness- can be seen as building on established scientific and practice traditions such as technology assessment and is to be contrasted with Responsible Research and Innovation (RRI) which was developed within the European Commission, is based on six keys, and is promoted through its Research Framework Programme Horizon 2020. Because both discourses are closely related and call for aligning research and innovation with societal needs, we use the term RRI to refer to both aspects.

Importantly, as we discuss below, the RRI approach calls for a discussion of the notion of responsibility. The significance of a clear concept of responsibility in the RRI discourse was pointed out early on (Grunwald 2011). Rather than the fragmented, individualistic, and role-oriented approach to responsibility (according to which different stakeholders are responsible for different aspects of the research and innovation process) (Fisher and Rip 2013), RRI proposes a richer concept intended to ensure the ethical sustainability and desirability of science and innovation outcomes. First, responsibility is seen as collective, involving researchers, innovators, funders, policy makers, and other stakeholders like universities, business / finance, government or civil society, and as distributed throughout the research and innovation process (Von Schomberg 2013; Owen, Macnaghten, and Stilgoe 2012; Stilgoe, Owen, and Macnaghten 2013; Owen, Heintz, and Bessant 2013). It is therefore characterised by a high degree of interdisciplinarity (Delgado, and Åm 2018) Second, responsibility is considered proactive more than reactive, that is, the focus is not on accountability for potential unwanted outcomes, but rather on shaping scientific practices by making practitioners commit to socially desirable goals. This entails that responsibility is not exhausted by legal compliance: it requires engagement with society and understanding of social goals. Responsibility is thus understood as the combination of a responsible process *and* desirable outcomes (Stilgoe, Owen, and Macnaghten 2013; Von Schomberg 2012).

The HBP's approach to RRI

The authors of this article are members of the team doing research on and implementing RRI in the HBP. The HBP offers itself as a basis for a reflection on RRI for several reasons. As an EU Flagship Project, it is an exceptionally large project, with a budget of about €450 m, a duration of 10 years (2013–2023), and more than 100 partner organisations with hundreds of researchers, technicians, administrators, and other staff involved (Mahfoud 2021). Moreover, the project is located at the intersection of neuroscience, medicine, and information and communication technology (ICT) (Amunts et al. 2019) – domains that independently and collectively raise a host of ethical, social, and regulatory issues (Salles et al. 2019). The call for implementation of RRI has incorporated social sciences and humanities disciplines mainly through the HBP's 'Ethics and Society' subproject tasked with identifying, reflecting upon, and managing the ethical, social, and philosophical issues raised by the project. To the best of our knowledge, the HBP represents the largest investment into RRI in any one project or programme.

From its start, the HBP has attracted the attention of external observers interested in some of the ethical issues it raises (Lim 2013). The breadth and complexity of the project, the fact that it touches on many sensitive and controversial questions, ranging from personhood to the understanding of mental health, from fundamental questions of

consciousness to practical issues of research ethics, has meant that the questions that RRI needs to cover in the HBP are broad and diverse (Rose 2014; Christen et al. 2016; Bringedal et al. 2017; Salles, Evers, and Farisco 2019; Stahl et al. 2019). RRI has been integrated into the HBP since its very beginning (Salles, Evers, and Farisco 2019). In order to structure RRI-related activities, the Ethics and Society subproject adopted the RRI AREA framework (anticipate, reflect, engage, and act) adapted from Stilgoe, Owen, and Macnaghten (2013) and implemented by the UK Engineering and Physical Sciences Research Council (Owen 2014).

As an EU-funded project, the HBP has also engaged with the EU RRI keys: public engagement, open access, gender, ethics, science education, and governance. While the HBP has addressed all of these, not all of them have been integrated into its Ethics and Society subproject (the organisational home of RRI). Instead, they have been partly distributed among other sub-projects.

To illustrate, the HBP is, among other things, a big data integration and provision project (Fothergill et al. 2019a). Data governance is therefore key to the project and to the development of the infrastructure. However, responsibility for ensuring the openness of data in the project falls mainly outside of the RRI team. Similarly, questions of diversity and gender equality were identified as relevant early in the project (Fothergill et al. 2019b), but were integrated into the management aspect of the project and only became part of the work of the RRI team in the latest phase. Such work is carried out in line with the European definition of RRI, which asks for monitoring and improving the gender balance in science, encourages reflection on gender and diversity in research, engaged communities, and stakeholders in general and calls for taking appropriate actions. In turn, the HBP's education programme which undertakes diverse educational activities (open to HBP members and externals) including science education outreach activities in collaboration with science museums is part of the remit of the HBP's management team, not the RRI team. The remaining EU RRI pillars, i.e. (research) ethics, public engagement, and questions of governance to support RRI in the HBP have remained in the remit of RRI team.

Importantly, while the HBP is active in all the areas of the EU's keys of RRI, its RRI activities align closely with the AREA framework.

Stages, processes and outcomes of RRI in the HBP

The HBP's final phase started in April 2020 and will end in 2023. We have provided detailed accounts of our work during the first 8 years elsewhere (Salles et al. 2019; Aicardi et al. 2018; Fothergill et al. 2019a; Stahl et al. 2019; Aicardi et al. 2020; Salles and Farisco 2020). We have published Opinions on three topics: data protection and privacy (Salles et al. 2021), responsible dual use (Aicardi, Bitsch, Bådum, et al. 2021), and artificial intelligence (AI) (Aicardi, Bitsch, Burton, et al. 2021). We briefly outline our key RRI-related activities using the main headings of the AREA framework.

Anticipation is the first aspect of the AREA process. Anticipation was addressed through the creation of the HBP Foresight Lab charged with facilitating anticipation on possible future uses and applications of HBP, basic scientific research. Anticipation was organised through structuring research and debate about possible and likely outcomes as well as integrated anticipation activities in all HBP RRI work.

Reflection is the second aspect of the AREA framework. It is key to the integration of social, ethical, and scientific inquiry. One approach used in the HBP is philosophical reflection intended to open a productive space for identifying and assessing scientifically relevant ethical, philosophical, and societal issues, carrying out self-critical analysis, and thus contributing to the interpretation and understanding of the research itself and of the mutual relevance of science and ethics.

Our engagement efforts built on ideals of deliberative democracy with the aim of inviting different communities to deliberate and debate on the aims, visions, and challenges of the project and the topics under investigation. During the first seven years of the HBP, we organised three major public engagement efforts across Europe engaging more than 3300 citizens, and we hosted several face-to-face as well as online expert engagement workshops and debates.²

The HBP RRI team has interpreted the Action category as encompassing all those activities that help scientists, researchers, and other stakeholders to meet their various responsibilities and implement RRI in practice. In this sense, action includes not only a focus on practical outcomes arising from anticipation, reflection, and engagement, but also RRI-related work revolving around ethical and notably legal compliance. Many of these activities were bundled in what was called Ethics Support, which included compliance management, ethics-related data governance and data protection, and additional mechanisms to support the HBP's Ethics Advisory Board and the Ethics Rapporteur Programme (Salles et al. 2019)

The Ethics Rapporteur Programme is an interdisciplinary collaborative network, which in a bottom up and dialogical way traces ongoing emergent ethical and social issues in a self-reflexive manner, beyond standardised compliance processes (Stahl et al. 2019). The strategy has been to have each subproject be represented by a rapporteur who can anticipate and address ethical and social issues raised by the relevant research and outline them regularly in a 'one-pager', a living written tool that helps the HBP to gain an ethics overview of the whole project. Rapporteurs also play an important role in other HBP RRI-related groups, such as the Dual Use Working Group and the Data Governance Working Group (Grasenick and Guerrero 2020).

This brief overview does not provide a comprehensive report of every RRI initiative in the project, but it illustrates how we have interpreted RRI and how this has structured our work.

The focus of [Figure 1](#) is on the organisational structure of our RRI work. RRI work in the HBP has always been underpinned by research-based activities and it has led to a stream of outputs, including peer reviewed articles, newsletters informed by stakeholder and citizen engagement, Ethics and Society Opinions and various guidelines for ethical compliance and management. Our publications often touch on many of the lessons learned that we discuss next.

Lessons learned

The 'lessons learned' included here are those that as this article's authors we consider to be particularly pertinent, be it because they have required attention to and management of particularly difficult issues, or because they have confirmed or challenged our understanding of RRI and its literature. The insights presented here are the outcome

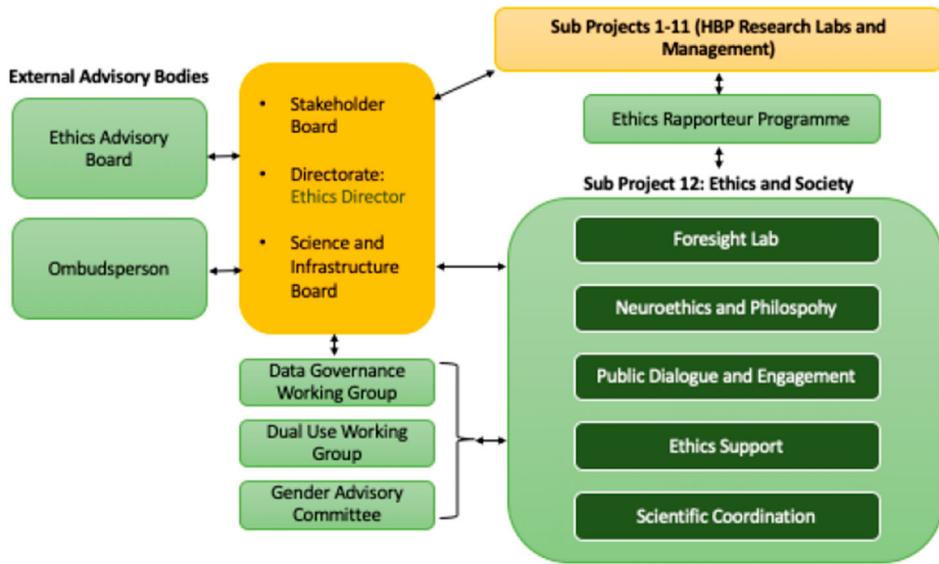


Figure 1. Organisational structure of RRI work in the HBP (adapted from Salles et al. 2019).

of internal reflection, debates and numerous interactions over the lifetime of the project. They thus do not fit a neat methodology description but are nevertheless based on a detailed and critically reflected understanding of the underlying aspects. Some of our experiences of implementing RRI in the HBP were perceived as successes, others highlighted challenges, and some did both. We describe these lessons and summarise key insights below.

Extensive public engagement can inform project decisions

Engagement of a diverse range of actors in anticipation, reflection, and inclusive deliberation – closely tied to policy and decision-making – is one of the central building blocks for supporting and developing structures and cultures of collective responsibility in the RRI framework (Owen, Macnaghten, and Stilgoe 2012). In the HBP, we undertook extensive public engagement activities. Outcomes from those activities contributed to the Ethics and Society Opinions (see section 3.4). Furthermore, engagement activities have been recognised within the project and by reviewers and the EC as a key element in community building in the future EBRAINS research infrastructure. As we explain in section below, inclusive community building is a central part of the strategy for infrastructure development in the final phase of the HBP (set up as a collaborative effort across the project with strategic support from the HBP Infrastructure Operations Director). However, while overall public engagement activities can inform project decisions and development, we confront some challenges.

One is the well-known challenge of pointing to a direct impact of the engagement activities on stakeholders, experts, and lay publics. It is hard to track and follow the fate of specific recommendations and outcomes as they move through various project partners and working groups. In addition, it is not always clear whether our outputs live up to lay publics' desire for increased transparency in the form of clear, detailed,

honest, easy to understand and easy to find information. Future work on the implementation of RRI would benefit from considering these issues.

In practice compliance issues tend to dominate the RRI agenda

As an approach to research and innovation governance that encourages anticipation and reflection, RRI is by nature unpredictable and difficult to capture. The topics of relevance in a broad project like the HBP fall within a spectrum of uncertainty, ranging from the highly speculative, such as the potential impact of creating artificial consciousness, to the well-defined, such as legal compliance in order to address neural privacy protection concerns. In basic research, even previously well-defined issues may turn out to be less clear than expected, for example, when new research raises questions concerning whether established anonymisation methods of human fMRI data may be reversible, leading to unpredicted legal challenges.

The urgency of dealing with clear legal issues, such as data protection or research ethics compliance, is relatively easy to convey within and outside of the project. The introduction of the General Data Protection Regulation (GDPR 2016) is a case in point. In the HBP, the coming into force of this pan-European regulation led to high levels of attention across research communities and to the possibility of resource reallocation for the creation of the position of a Data Protection Officer. Another example is research ethics compliance. Research ethics is well regulated in the Horizon 2020 Framework Programme, and in many cases based on statutory law. The use of animals in research, for example, is regulated in the EU Directive 2010/63 and has been translated into national law by Member States (Olsson et al. 2017). Aspects of research ethics that have to do with research on humans are also extensively regulated, e.g. with regards to consent requirements, subject protection, etc. Researchers working on biomedical topics are typically well-aware of the regulatory environment and accustomed to complying with it. The HBP raises questions about research ethics and legal compliance due to its size and organisational complexity. But even if the project required significant efforts to institute processes that collect and communicate compliance data, from a conceptual point of view, most of this work has been relatively straightforward.

Work on dual use presents an interesting case. Compliance with export restrictions is one of the issues to be checked during research compliance management, even if of little relevance in the HBP where most of the work is basic research. But the HBP RRI group's work on dual use goes beyond the immediate legal issue such as export restriction and facilitates reflection on broader political, security, intelligence and military uses of concern (Mahfoud et al. 2018; Ulnicane 2020b; Aicardi, Bitsch, Bådum, et al. 2021), an approach that has been well-received within and beyond the project (Garden et al. 2019; Ienca, Jotterand, and Elger 2018). These examples show that an undue focus on legal requirements can limit the implementation of RRI by narrowing the discussion, instead of promoting thinking about consequences, reflecting and reaching out to stakeholders.

Complying with existing legislation is a necessary condition for the societal licence to operate for science, research, and innovation. Without going too far into philosophy of law (Marmor and Sarch 2019), one can see laws as the expression of the will of society and in many cases as representing accepted moral preferences (e.g. with regards to

how animals can be treated). RRI, understood as the process of aligning science and society, therefore plays a role in ensuring legal compliance, highlighting possible issues, and providing support for researchers. There is a danger, however, that the generally accepted need to comply with legislation and regulation in practice might lead to a narrowing of the understanding of RRI. The purpose of RRI is clearly much broader than compliance: activities related to anticipation, engagement, and reflection cannot and should not be reduced to compliance with and adherence to current laws and regulations

Interdisciplinary collaboration is challenging when implementing RRI

Interdisciplinary and potentially transdisciplinary collaborations are crucial for the implementation of RRI (Stilgoe 2015; European Commission 2013). However, in our experience there are various challenges to such collaboration. The RRI team members have engaged in diverse collaborations across the project initiated by themselves and others within the project. These collaborative activities have revealed a diversity of views towards RRI. Some scientists appear to perceive time spent on social and ethical issues as a distraction from their scientific research whereas others are eager to engage with the social and ethical aspects of their work.

The challenges of interdisciplinary collaboration arise not only when RRI team members work with neuroscientists, computer scientists, and others in the HBP but also when working with colleagues from the RRI team itself. The RRI team's members have different roles as researchers, administrators, and practitioners, and they are based in different types of institutions, such as universities, foundations or companies. Furthermore, team members have diverse disciplinary backgrounds including philosophy, neuroethics, computer ethics, sociology, gender studies, political science, Science and Technology Studies (STS), and law, which leads to questions such as what topics to prioritise, how to evaluate the work, who is more qualified to address specific questions, and on what grounds.

Interdisciplinary work raises questions about research itself, for example, how far one can really understand the content of one's collaborators' science (O'Rourke, Crowley, and Gonnerman 2016). In turn, joint publications may raise questions about established authorship criteria, such as the 'agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved' (ICMJE 2020). Another well-established challenge raised by interdisciplinary publications is the determination of what counts as high quality research and whether interdisciplinary publications count for academic promotion, which still often takes place within disciplinary silos. In practice, this might result in interdisciplinary co-production within the project being too risky for researchers whose evaluation and promotion at their respective institutions is likely to be organised along scientific disciplines (Balmer et al. 2016).

Interpretations of RRI continue to be subject of debate

Eight years into the project, the exact definition and delimitation of RRI continues to be a topic of discussion within the HBP in general and within the RRI team in particular. This

may be partly due to different disciplinary views of RRI, different roles in the project, and personal dispositions. The contested nature of RRI surfaced very clearly during the process of writing this paper, with various views as to how RRI should be portrayed, how our work should be described, and what conclusions can be drawn from it.

How one views RRI shapes how one interprets some of the topics we have addressed in our work. It is true that some differences are to be expected in interdisciplinary collaborations; often those differences enrich joint work by leading to the integration of different perspectives. They become a challenge, however, when a group such as the HBP RRI team is expected to speak with one voice: existing differences lead to the question of whose voice speaks for the whole group and why. There is a potential for power struggles on the one hand, and marginalisation and exclusion of valuable expertise and competencies, on the other which is a challenge not limited to but well recognised in interdisciplinary research (Bammer 2013)

The discussion of the interpretation and role of RRI is not confined to the RRI team itself but has implications for the overall project. The most prominent collective outputs of the RRI team have been the three already mentioned Opinions (Data Protection, Dual Use, AI) developed by the RRI team members in collaboration with internal and external stakeholders, including the members of the Ethics Advisory Board. The Opinions are joint documents that attempt to identify, reflect upon, and offer recommendations for addressing the ethical issues arising from the project's research. Following consultation within the project, they have been published on the project website. However, the process of writing and publishing these Opinions has at times been contentious, with some scientists questioning both the RRI team's mandate to provide recommendations to the project and the status of the Opinions as public documents. Interestingly, in two recent cases an initiative has come from scientists in the governing bodies to turn these recommendations from the RRI team into more collaborative endeavours. In the case of the Dual-Use Opinion, the governing bodies decided to launch a project-wide working group to prepare and implement follow-up actions, while in the case of the AI Opinion, they suggested starting a broader interdisciplinary collaboration to work on the identified issues.

Implementing RRI reveals gaps in knowledge of substantive issues

So far, we have focused on our experience dealing with procedural aspects of RRI, from issues arising from interdisciplinary collaboration to the implementation of regulation. Implementing RRI in the HBP has made clear, however, beyond procedural open questions, there are also many substantive issues that remain open and require further examination.

One such issue is gender and diversity. In addition to questions of equality in research teams, aspects of diversity (e.g. gender, ethnicity, age, race, (dis)ability, career stage) have been addressed by guidelines, 'diversity in research' workshops, presentations, and incentives such as the Best Paper Awards (see Grasenick 2019). In line with EU policies like 'Science with and for Society', and the RRI keys, the focus had to be on gender more than on other diversity dimensions thus limiting an intersectional approach (Fothergill et al. 2019b). Research directions such as feminist neurosciences or neurofeminism seem promising at first glance since these 'evaluate practices of knowledge production

within neuroscience’ – one of the main research areas in the HBP- and ‘seek for alternative models of non-generalized interpretations, which are based upon intersectional categories such as gender, ‘race,’ and age’ (Schmitz and Höppner 2014).

There are other pending substantial questions, such as whether defacing of fMRI files can count as anonymising them (Ravindra and Grama 2019), whether and under which circumstances neurodata from genetically modified primates can be made available through the HBP, and how philosophical considerations on consciousness (e.g. definition of criteria for ascribing it to others, including animals and AI) can be reflected in data collection and sharing.

An additional concern emerges from the fact that despite being in what we can call a multicultural project the issue of how to acknowledge, understand, and manage the impact of cultural considerations on research and innovation in general and their implications for HBP research in particular and for EBRAINS in the future has remained unexplored. Aware of the significance of this topic and of the potential role of culture in promoting more ethically sustainable research in general, the Ethics and Society team has started an examination of this issue using RRI-inspired conceptual and practical tools.

The examples above suggest that implementing RRI is not easy or straightforward, neither procedurally nor in terms of the substance of the relevant questions. This leads to a final lesson in this paper, namely that the success of RRI is not only practically difficult to measure, but also conceptually difficult to define.

Success of RRI implementation is difficult to prove

Because the work described is the implementation of RRI within a project, we have very limited ability to affect the framework within which the project is realised, both in terms of scientific research and of which ethical and social issues are managed and regulated. Some larger issues that are difficult to address, and probably impossible to resolve at the project level include fundamental conceptual questions, such as the identification of societal needs in a transnational setting and their incorporation in research and innovation, and societal preferences, such as those related to protection of personal data. An additional issue is that of the scope of RRI within the project. One recurring challenge to our work in the HBP is that RRI remains blind to some pressing ethical and social issues that project participants perceive. Conversation with colleagues from scientific and technical disciplines often point to issues that are not typically discussed in the RRI literature, for example, struggles with what is perceived as excessive bureaucratisation of research processes. For some colleagues this as an ethical and RRI concern, as it relates to governance and reduces the resources and freedom to do research, and yet, this is not generally recognised as a specific RRI-related problem in the literature. Additional issues include questions concerning transparency in decision-making and strategic development, key topics for RRI with its focus on inclusiveness.

The open question of the exact scope and remit of RRI exacerbates the well-discussed challenge of providing evidence of the success of RRI. Despite much research on measuring the impact of RRI (Expert Group on Policy Indicators 2015; Holbrook 2019; Mejlgaard, Bloch, and Madsen 2019), how to measure RRI success or impact, and whether it even makes sense to attempt to do so, remain as open questions. The logic of

current research-funding processes demands such measures, but the value of some of our key performance indicators (i.e. number of papers published, number of ethics approvals reviewed, number of workshops held) is difficult to assess, as is the quality of these activities and their longer lasting impact. Finding evidence for the broader culture change that RRI is expected to bring about remains challenging. It is therefore not surprising that our widely visible work attracts criticism in general terms (Maasen 2018).

Key insights

These key insights are derived from eight years' worth of work on RRI in the HBP. First, RRI remains debated, contested, and in flux at a conceptual level, both in terms of processes and in terms of the substantive issues it can cover. This calls for further examination of the very components that constitute RRI, i.e. anticipation of future developments, engagement with relevant stakeholders including lay publics, and reflexivity of projects where RRI happens and of the groups and individuals who do the work. Expectation management is key to RRI. We should be careful not to overpromise. RRI cannot eliminate the uncertainty of the future or the certainty of existing disagreements and social dynamics. RRI can aim for desirability, acceptability, and sustainability of research and innovation processes and outcomes, but there is no guarantee that these will be achieved. RRI should not be understood as a solution to a problem, but as a process that helps scientists, RRI scholars and practitioners, and diverse stakeholders and publics to reflect better on research and innovation, even if it is unable to guarantee that such processes will lead to societal closure. RRI cannot be clearly and statically defined. It needs to form part of, and therefore co-evolve with the science that it is integrated into.

This view of RRI raises one pending issue that merits further attention in the RRI literature: What happens to and with RRI when the active and funded phase of RRI integration into a project ends? This is a practical so far unanswered question for us, and one that is important for the RRI community in general.

Future work: towards responsibility by design

The intended official legacy of the HBP is EBRAINS, which is planned to take the form of a European Research Infrastructure (Ulnicane 2020a). As such, EBRAINS calls for different ways of thinking about and implementing RRI. But the general topic of the transition from a funded project to a longer-term embedding of RRI is relevant to the RRI discourse more broadly.

The topic is discussed with regards to RRI in industry (van de Poel et al. 2020; Yaghmaei 2018; Martinuzzi et al. 2018), where the outcomes and results of research and innovation activities tend to be products or services that are made available through market mechanisms. But in general terms, the discussion about what happens when processes of research and innovation are completed and move into production and use is limited. In our case, the lack of practical guidance regarding how to integrate RRI in the results of research and innovation activities is complicated by the fact that the main envisioned outcome of the HBP is a European Research Infrastructure, which is expected to provide the basis for further research and innovation – but in a very different

institutional and funding environment. The transition we are now facing is, therefore, of interest to the RRI community as a whole, if it wants to ensure that RRI will continue to shape science, research, and technology development in societally acceptable directions. Next, we discuss our attempts to move beyond project-oriented RRI research and practice towards the integration of the relevant responsibilities of RRI into the ongoing activities of the EBRAINS infrastructure. In particular, we propose that the transition from ongoing funded research and innovation projects to the implementation and use of the outcomes of these projects in a subsequent research infrastructure might benefit from a shift from RRI towards responsibility by design (RbD).³

The related term ‘responsible by design’ is not new. It was already used in the evaluation of early RRI activities with Technopolis & Fraunhofer (2012, 29) who stated that ‘Research should be “responsible by design” and thus account for societal risks, benefits and impacts right at the beginning.’ More recently, the non-governmental organisation *doteveryone* (Miller and Ohrvik-Stott 2018) proposed the creation of a unified responsible by design programme in the context of an examination of some of the societal and ethical issues raised by digital technologies and the need for regulation. We adopt the term here because we believe that it expresses the challenges caused by the transition from the research project HBP to the EBRAINS infrastructure, which is currently being designed, including its technological platforms but also its social and organisational structure.

The intended design of EBRAINS is still under development and thus its eventual shape is uncertain. The same can be said of the EBRAINS RbD model which is developing together with the research infrastructure. Still, it is evident that EBRAINS must be designed to ensure responsible actions and outcomes (by the leadership, management team, service providers, and the users). If it is to be ethically and socially sustainable and desirable, EBRAINS will require making responsible choices that can shape the application and use of its tools, resources, and services. The choices will have to be made on the basis of a set of concerns very much impacted by contextual factors, including the often-complicated relationships between funders, management, service providers, researchers, technologies, and datasets within the research-infrastructure ecosystem. Because those factors might present challenges to the integration of societal values for stakeholders operating from different regulatory environments the goal is to develop different technical, ethical, social, and legal mechanisms that provide solutions to both identifiable and unanticipated problems (Eke et al. 2020). Our suggestions below give an indication of how this might be achieved. We finish this section with a more theoretical discussion of RbD.

Organisational integration of RRI

Initially, the concentration of RRI work in one dedicated sub-project in the HBP had the advantage of providing a focus for RRI. In the final phase of the project, some RRI work was distributed across the project and directly embedded in diverse work packages in the hope that this will strengthen further RRI integration. Inclusive community building is located in the central infrastructure work package, while other RRI-related activities such as data protection, data governance, and compliance management are also distributed across the project.

Furthermore, there is in the HBP a dedicated RRI work package, which focuses on overarching issues of relevance to the entire project, from dual use, researcher awareness and neuroethics to public engagement and gender, diversity and inclusion. The central coordination of all RRI-related activities, including the Ethics Rapporteur Programme and those embedded in the scientific work, also remain part of the central RRI work package.

The HBP is remodelling some of the RRI-related groups to enhance their ability to affect the framework within which some of the ethical and social issues are addressed. For example, the Gender Advisory Committee is being remodelled to emphasise diversity and inclusion. As RbD is intended to be value sensitive, that is, take into consideration societal values for the design itself, it is essential that it considers all societal values, in all their diversity, including identity and the different ways in which it can be conceptualised and thus impact the discussion of the issues.

A key question that we are currently exploring is how RRI activities will be represented in the organisational structure of the EBRAINS infrastructure. This question does not have a straightforward answer because, as noted above, the organisational structure and future of EBRAINS itself is still under development. In order for the RbD model to be useful, it must embed RRI effectively. While this discussion is just starting, requirements driven by law, such as data protection and security or research ethics compliance, might be more easily implemented than broader RRI activities such as those intended to enhance institutional capabilities for foresight, societal engagement, and follow-up action. Considering the planned financial structure of EBRAINS, which as a European Research Infrastructure will need to be core-financed by Member States, questions of requirements and prioritisation are certain to arise.

Community and capacity building

As noted above, responsibility by design as we use the term here focuses on sustainability and long-term impact after the considerable funding that the project receives ends. For the EBRAINS research infrastructure, this will depend on its ability to mobilise the relevant scientific communities that make use of the infrastructure provisions. Accordingly, the development of such scientific communities is a key task for EBRAINS. It furthermore offers a unique opportunity to integrate RRI principles and practice into these nascent communities. Recognising the benefits that can be derived from having a community of EBRAINS stakeholders who actively apply and promote RRI principles, we have among other things, begun a community building initiative which focuses on building an RRI community around EBRAINS. The EBRAINS RRI Community building effort is based on the work we previously did on public engagement with experts and stakeholders. Furthermore, the effort is based on principles of Open Research Agenda Setting (ORAS), combined with process and outcome requirements of the RRI framework. At the heart of the strategy is the aim to allow emerging communities to influence the development, agenda, and priority setting of the future EBRAINS infrastructure. The public engagement group is part of shaping the strategies, activities, and descriptions of the EBRAINS community and its values going forward.

The creation of communities is, however, only the first step. From an RRI perspective, the key question is which forms of knowledge and skills these communities can or should

have. We therefore have developed a capacity-building programme that targets all future user communities of EBRAINS. An effective RRI capacity building hinges on the institutionalisation of RRI principles in the culture of the EBRAINS community. As Eder (1996) suggests, it is necessary to see the institutionalisation of common principles as requiring a continuum of both cognitive and normative processes which must be interlinked to produce the required results. Thus, the capacity building activities we have designed go beyond a mere focus on knowledge (or cognition): they aim to be practically relevant to EBRAINS stakeholders and to enable their continued use in practice so as to foster a culture of responsibility in the research infrastructure. They are the result of a process of reflexivity, of the knowledge and experience acquired in the past 8 years, and long-term engagement with relevant internal and external stakeholders, e.g. via working groups whose membership cuts across both the diverse teams of the HBP as well as at forums like conferences, workshops, etc. where the relevance and importance of RRI is regularly highlighted.

From research to innovation and commercial exploitation

The facilitation of commercial exploitation and engagement with industry are relevant for the HBP's final phase. Research on bio-inspired modelling and neurorobotics, for example, has led to several technologies that are on the cusp of commercialisation. The transition from basic research to applicable and marketable innovation is expected to be relevant for the EBRAINS infrastructure, which may be open for commercial research.

For these reasons, the identification of issues related to the exploitation and commercialisation of emerging applications has become a crucial task. This line of work will identify and analyse ethical, social, and RRI issues that arise in the context of the development and commercial application of technologies, methods or services innovated in the HBP. This includes a concern with the societal, political, economic, and environmental consequences of emerging applications, both in terms of possible benefits and opportunities, as well as potential problems, risks, and unintended consequences.

In addition, we plan to undertake an examination of the ethical and social aspects of the international transfer of technologies and applications. This line of work will reflect on the ethical, social, economic, and political aspects of the international transfer of AI, bio-inspired modelling and neuro-robotics applications developed in the HBP to other world regions, and the development of corresponding ethical and RRI criteria. Global differences in wealth, culture, scientific capacities, as well as political and regulatory systems affect the ways in which new technology products, applications, or services are used, regulated, and commercialised in different contexts. Based on insights gained in these steps, we aim to develop an ethics and RRI methodology that can inform research and exploitation. This methodology shall provide clear procedures and criteria for researchers within the HBP and EBRAINS, as well as other scientists and innovators in firms, to identify and evaluate key ethical and social issues of emerging applications and their commercial use. This methodology will form part of the knowledge base and capacity-building activities mentioned previously. We are working with the HBP innovation team to ensure that these ideas and methods can be integrated into the commercialisation activities.

Global RRI engagement and ensuring societal benefit

Given the limitations of RRI implementation at a project level, broader outreach is required to address wider and not project-specific questions. This is not something that an RRI team in one project can achieve unilaterally, but which requires collaboration with other teams. In addition, several issues we address and many of our insights and strategies to addressing issues are likely to be of interest to other brain initiatives and to neuroscience communities in different countries. From the beginning, we have explicitly recognised the need for strengthened international collaboration on the identification of issues and neuroethical reflection. In practice, this has resulted in joint work with the existing and emerging international big brain initiatives. At the project level, reflection on neuroethical and societal issues has been further enhanced by the creation of the International Brain Initiative. Intended to foster global efforts to understand the brain, in its declaration of intent the IBI specifically acknowledged the need to address the ethical and social challenges raised by brain research and calls for collaboration in ‘the fields of neuro-ethics, agency, responsible data stewardship, and cerebral privacy protection’ in engaging ‘in a meaningful dialogue with citizens, patients, and all relevant communities to understand their concerns and communicate transparently on the opportunities and challenges arising.’⁴ The HBP has been a member of the IBI Neuroethics working group since its creation and the HBP’s RRI team is currently working with different Brain Initiatives on several topics including the role of public engagement in building new understandings of barriers and possibilities for international collaboration, the possibility of sharing RRI practices globally, and assessment of strategies for the integration of neuroscience and neuroethics (Miller and Page 2007). Furthermore, members of the HBP are engaged in and contributing to many other global interactions with researchers and stakeholders, for example, the development of the first international standard for responsible innovation in neurotechnology launched by the Organisation of Economic Cooperation and Development (OECD 2019).

From RRI to RbD

We propose that RbD may be able to overcome some of RRI’s practical limitations. The transition from research and innovation activities, which are typically undertaken in a project environment, to the actual use of the outcomes of research and innovation, which are typically undertaken in a production environment (or an infrastructure, in our case), calls for a different way of thinking. The core idea behind RbD is the need to find ways to integrate attention to concerns and possible negative future impacts of a development into a technology that will be part of a larger social structure.

The concept of RbD refers to activities of reaching out to stakeholders and debating both the concerns, and the desirable endpoints of the development being worked on. While we acknowledge that the focus on research and innovation activities is RRI’s natural starting point, we believe that within RRI such focus is still limited if the goal is to promote desirable, acceptable, and sustainable processes and long-term outcomes. Despite its original intention, in practice RRI is typically brought in after the main decisions are already made, e.g. to launch a major research project or research infrastructure. In such cases, RRI has the rather limited tasks to legitimise and shape these

initiatives on the margins. In contrast, RbD seeks to make responsibility part of the preparation and making of such decisions, which draw on evidence of anticipation, reflection, and engagement to decide whether and what kind of a new research and innovation initiative is launched. Moreover, in RbD responsibility should not be limited to research projects and laboratories where its implementation is limited by macro-level processes, academic capitalism, and marketisation of universities (Glerup, Davies, and Horst 2017); RbD should also aim to implement responsibility at the level of academic and economic system, funding policy, and the organisation of universities and companies.

A further issue raised by RRI is that in practice it remains an external imposition on researchers and scientists. Despite successful work with scientists and recommendations to integrate RRI considerations 'at the planning stage and design of technological development', RRI activities remain often a separate and self-referential activity that is predominantly the remit of the RRI team. This can result in a disconnect of RRI activities among different levels, notably the policy, funding, and research levels. While imposing RRI via funding evaluation criteria as incentives is suitable for projects, the question remains whether the imposed principles will have a sustainable impact on the involved researchers, and moreover on the organisations of which they are part.

Progressing beyond RRI, however, raises several questions. For our immediate purposes, a relevant one is what set of concerns a research infrastructure like EBRAINS should pay attention to. Some of the examples provided here, including data protection and privacy, dual use, AI, and community building, have uncovered manifold issues related to human rights, law, justice, security and definitions of responsibility, societal benefit, and societal engagement. But there are other concerns as well, for example, which values and principles should be embedded in the design of RI infrastructure, e.g. respect for human rights, justice, autonomy, beneficence and non-maleficence, animal welfare principles. Addressing them requires appropriate processes for citizen and stakeholder engagement, and social responsibility mechanisms by which abstract principles and values may be discussed, deliberated, decided on, and eventually implemented in the specific use context of a research infrastructure developed for the common good. It also requires further reflection on how to integrate ethical principles, values, and societal needs.

We do not assume that the questions above have clear-cut and unproblematic answers. Finding the answers in practice will most likely require what Kuhlmann, Stegmaier, and Konrad (2019) call 'tentative governance', i.e. the use of governance mechanisms that are open to learning and adjustment which is particularly relevant in cases of emerging sciences and technologies characterised by high uncertainty about their future development and implications. This is what the HBP RRI team is trying to achieve, and this is what is leading us to develop RbD. We are aware, however, that as we are writing this during the early stages of the implementation of RbD in EBRAINS we are not currently in a position to assess their success. Interestingly, the fact that the consequences of these measures will only become visible after the end of the funded RRI activities means that it will be very difficult to measure them: another challenge for RbD.

Conclusion

In this article, we have reviewed how RRI has been interpreted and implemented in the HBP. We have pointed to some key lessons, both in terms of successes and in terms of

ongoing challenges and how we have used them to plan our next steps for the remainder of the project and for the post-project infrastructure stage.

We began by identifying two related research questions. The first one asks what we can learn about the strengths and limitations of RRI from the implementation of RRI in a large multidisciplinary research project. The answer starts with the observation that any project, even a lengthy one like the HBP, remains a temporary endeavour that must develop the relevant structures and procedures to support information flow and involvement / participation reaching all members, assist members' learning processes, and develop the necessary steps to implement RRI principles. While doing this from within the project can be a good way to implement RRI, the benefits and risks involved – potential loss of critical distance, possibility of being used to legitimise scientifically risky projects with various degrees of scientific significance – remain difficult to balance. The 'lessons learned' section addressed some of interest for the RRI community.

The second research question was: how can we build on our specific experience to go beyond the current RRI discourse in theory and practice? To answer this, we have focused on the still open question about what happens to RRI after the end of project-related funding. The main concern is how RRI can become institutionalised in the products and outcomes of research and innovation. HBP's main product will be a research infrastructure intended to facilitate future research. The 'product' calls for ways of embedding RRI, so that this future research will be guided towards principles and practices of RRI. This raises several interesting questions for the broader RRI discourse.

The transition from integrated RRI in an EU-funded research project to integrating RRI in a European Research Infrastructure is a unique and idiosyncratic characteristic of the HBP. However, the principle of moving from a research project to a sustainable outcome of research and innovation activities is typically part of research and innovation trajectories. We have used the term RbD to denote this idea, as an aspect that points to the integration of RRI principles and processes into future use and exploitation of products and outcomes of research and innovation. For RRI to become truly successful, it must be part of the research and innovation process and product and not seen as an external requirement/complement. This requires major changes in research and innovation governance, policy, and funding. The concept of RbD points in this direction, and we hope that it will be of interest to the RRI community in thinking through the difficult question how the legacy of RRI can be ensured beyond the reach of immediate RRI interventions.

Notes

1. In this article, we use the term 'infrastructure' in a specific sense of 'European Research Infrastructure' which are understood in the EU policy as 'facilities that provide resources and services for research communities to conduct research and foster innovation'. Source: European Commission 'European Research Infrastructures'. Available at https://ec.europa.eu/info/research-and-innovation/strategy/european-research-infrastructures_en (Last accessed 12 February 2021). For more on European Research Infrastructures, see Cramer and Hallonsten (2020).
2. An overview of seven years of engagement activities in the HBP: https://tekno.dk/wp-content/uploads/2016/09/Lessons_Learned_engagement_HBP.pdf.

3. The term was originally proposed by Richard Veyard: <https://rvsoapbox.blogspot.com/2018/10/what-is-responsibility-by-design.html>, accessed 08.06.2020.
4. <https://www.internationalbraininitiative.org/about-us>, accessed 15.09.2020.

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