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Responsible Innovation: A Pilot Study with the U.K. Engineering and Physical Sciences Research Council

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Significant time lags between the development of novel innovations (e.g., nanotechnologies), understanding of their wider impacts, and subsequent governance (e.g., regulation) have led to repeated calls for more anticipatory and adaptive approaches that promote the responsible emergence of new technologies in democratic societies. A key challenge is implementation in a pragmatic way. Results are presented of a study with the Engineering and Physical Sciences Research Council, the largest public funder of basic innovation research in the United Kingdom who, for the first time, asked applicants to submit a risk register identifying the wider potential impacts and associated risks (environment, health, societal, and ethical) of their proposed research. This focused on nanoscience for carbon capture and utilization. Risk registers were completed conservatively, with most identified impacts concerning researchers' health associated with nanoparticle synthesis, handling, and prototype device fabrication, i.e., risks that could be identified and managed with a reasonable level of certainty. Few wider environmental impacts and no future impacts on society were identified, reflecting the often uncertain and unpredictable nature of innovation. However, some applicants addressed this by including investigators with expertise beyond engineering and nanosciences supporting integrated activities that included life cycle and real-time technology assessment, which in some cases were also framed by stakeholder and/or public engagement. Proposals underpinned by a strong commitment to responsible science and innovation promoted continuous reflexivity, embedding a suite of multidisciplinary approaches around the innovation research core to support decisions modulating the trajectory of their innovation research in real-time.

KEY WORDS: Funding; nanosciences; research; responsible innovation

1. INTRODUCTION

It is acknowledged that there are often long time lags between the development and diffusion of disruptive and novel innovations (such as nanotechnologies), understanding of their wider impacts and associated risks (on health, environment, and society), and subsequent regulation (as a key form of governance).(1–5) Such time lags may run into many decades: for example, it has been estimated that toxicity testing of those manufactured nanoparticles currently available in the United States alone will cost between $249 million and $1.18 billion and take 34–53 years to complete.(6) This must be placed in the context of an innovation landscape that is rapidly changing (e.g., in the case of nanomaterials from passive nanoparticles to active structures and evolutionary systems).(7)

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These time lags are mirrored by the fragmented and often loosely coordinated nature of the actors involved in funding science and innovation itself, those investing in understanding of wider impacts and associated risks, and those with a role in technological governance.[2,8,9] To give one example, in the United Kingdom, basic innovation research is funded by (among others) the Engineering and Physical Sciences Research Council (EPSRC) and Technology Strategy Board; wider understanding of implications to environment, health, and society are then funded some time later by the Natural Environment Research Council, Medical Research Council, and Economic and Social Research Council; some time later again as evidence emerges, a governance response (e.g., amendment or development of new regulation) is recommended by the European Commission, U.K. government, and its regulatory agencies.[10] The temporal and spatial separation of these actors and their respective communities remains a significant barrier. The challenge has been to integrate these, implementing multidisciplinary approaches that can be enacted early on and at the same pace as innovation. Such approaches should be reflexive, participatory, and facilitate the opening up of the innovation process to modulation and adaptive management.[1,4,11–17] These include qualitative risk analysis deployed earlier in the innovation process,[18] adaptive and anticipatory governance,[1,2] technology assessment in its various forms (e.g., real-time and constructive technology assessment),[5][8,19] and other forms of technological "midstream modulation"[9] that can be framed by stakeholders and public engagement.[20,21]

Concepts such as better foresight, more responsive and adaptive governance, and participation in the context of technological innovation are not new (see review by Karinen and Guston[2]). A key issue is embedding them in a day-to-day operational context (i.e., implementation and practice). This must be achieved in a way that is acceptable, practical, and proportionate; one that does not stifle creativity and high adventure science but ensures that it is responsibly developed and sustainable. This requires coordinated working by actors such as research councils (whose remits cover innovation, understanding of implications and associated risks, and the placing of these in the context of the many benefits novel technologies can bring) as well as those who apply to their research calls.

The EPSRC is the largest funder of basic engineering and physical science and innovation in the United Kingdom. It takes its place at the earliest stages of the innovation process, which can be described in terms of "Technology Readiness Levels," or TRLs. Originally developed by NASA,[6] each level is associated with a number of institutional and or/corporate "actors" who play a role in the translation of creative ideas into commercial reality. The Research Councils fund early stage research (TRL I–IV), funding initial ideas through the proof of concept phase, typically to a prototype or demonstrator level. These can either be directed in particular themes (e.g., energy) or are proposed by scientists via routine "responsive mode" calls, which are intentionally unconstrained in terms of topic. Others in the United Kingdom, such as the Technology Strategy Board (TSB) and Knowledge Transfer Networks, then take the prototype on through scale-up, eventually into commercialization (for example, through university spin-out companies). This is a simplistic description of the innovation process,[9] which is a complex, nonlinear with networks of actors, and how it is funded (e.g., much innovation occurs within private R&D laboratories). However, the public funding of research in academic institutions, such as universities, remains a very significant catalyst for disruptive innovation and presents perhaps the earliest opportunity to embed a more reflexive, responsible innovation approach in an operational, real-world context.

In 2009, EPSRC undertook a pilot study to begin to understand how it could embed approaches that promote responsible science and innovation research within its funding activities. It did this in association with a major funding call, as an operational case study.[22] The call in question invited proposals that aimed to investigate the potential for nanosciences to make a novel contribution in the area of carbon dioxide (CO_2) capture and utilization. As such, this could be described as a call at the convergence of nanoscience and geoengineering, both of which have been identified as being

[5] Technology assessment has been described as a family of approaches that aim to reduce the human costs of trial and error learning in society's handling of new technologies, and to do so by anticipating potential impacts and feeding these insights back into decision making. Constructive technology assessment can be seen as a new design practice in which impacts are anticipated, users and other impacted communities involved from the start in an interactive way, and that contains an element of societal learning.[8]

[6] http://esto.nasa.gov//files/TRL_definitions.pdf

associated with large uncertainties with regard to environment, health and societal impacts, governance, and regulation.[1,11,15,18,23,24]

The 2009 EPSRC research call included proposals that enhanced the efficiency of carbon capture from fixed sources (such as power stations) and those intending to capture CO_2 from the atmosphere, for example, using distributed domestic photoreactors, which could also convert captured carbon to products such as fuels. This was a useful case study because, as one researcher applying to the call noted, "there is currently little published literature systematically appraising the social, economic, and environmental risks and opportunities associated with prospective technologies for the chemical fixation and utilization of CO_2, and role of nanotechnology therein." Furthermore, in 2009 the Royal Society report on geoengineering[15] specifically recommended that "a research governance framework is required to guide the sustainable and responsible development of (geoengineering) research."

The call was the last of three Nanotechnologies Grand Challenges administered by EPSRC on behalf of the U.K. Research Councils;[25] the first two focusing on the application of nanosciences for development of novel renewable energy and healthcare solutions. Grand Challenges are run in a "stage gate" process, whereby an initial budget (in this case approximately £5 million) is made available for research at the proof of concept stage and those with strong commercial potential then pass through the first stage gate and receive funding (in conjunction with others such as the Technology Strategy Board and industrial partners) for scale-up at more advanced TRLs. A feature of all the proposals received under the nanotechnologies carbon capture and utilization call was strong industrial partnership from the outset. This article describes the pilot study and its results before going on to discuss these and develop some initial conclusions regarding the operational enactment of the concept of early responsible innovation in public R&D funding schemes.

2. METHODOLOGY

The nanotechnologies for environmental solutions (carbon capture and utilization) call included a specific section on responsible innovation, the first time this had been attempted within a major research council funding activity. EPSRC stated in the call document that proposals should be "underpinned by a commitment to responsible nanotechnologies innovation." The call was run in two stages, with 10 full proposals invited from 20 initial expressions of interest received from the initial open call. At full proposal stage, applicants were asked to submit a risk register in tabular form, which required them to reflect on the wider implications of their proposed research, identify potential impacts, and qualitatively assess their associated risks. Applicants were provided with a proforma, which they were at liberty to use or amend as they saw fit. Applicants were asked that the risk register should:

1. Identify any potential environmental, health, societal,[7] or other impacts and/or any ethical concerns that may result from the innovation process.
2. Qualitatively provide an appraisal of risk for each identified impact and the level of uncertainty associated with it (e.g., impact A: low risk, high certainty).
3. Identify who in the project team would be accountable for managing any identified risks.

One of the risk registers received is provided in the Appendix for illustration. The choice of a risk register approach was made on the basis that this was one of the simplest risk analysis tools that could be easily employed, one that would not overburden applicants but would encourage them to begin to think about the wider implications of their research and who would be accountable for managing these. The call stated that information within the risk register was intended to be used as a tool to inform and support the applicants and EPSRC, allowing an upstream identification of impacts, risks, and associated uncertainties, which could be subsequently managed, e.g., through risk management or further research, where this was thought necessary. The call stated that risk registers would be externally peer reviewed and comments received by the reviewers would be considered by the funding panel as a secondary funding criterion, with feedback given to the applicants. Applicants were also told that the EPSRC's sister research council, the Economic and Social Research Council (ESRC), would be willing to make funding available for complementary high quality social science research embedded into the project proposals.

[7] These might include, for example, change in market supply chains and dynamics, potential visual impact and land usage of carbon capture reactors, implications of domestic fuel production from distributed units, or potential to introduce a "moral hazard," whereby belief that there is a technological solution for climate change might impact on behavior change.[15]

After submission of full proposals, applicants were interviewed by telephone to gain feedback regarding the risk register approach: how they completed it, its utility, and value. Risk registers were subject to external peer review. As part of the standard peer-review process, each proposal was also reviewed by a scientist from outside the engineering and physical sciences disciplines (e.g., the social sciences), who was asked to comment on the risk register and other aspects of the proposal that contributed to responsible nanotechnologies development. These reviews were considered alongside the others by the funding panel, which also contained a social scientist who evaluated the responsible innovation sections in all 10 proposals. The evaluations were discussed as secondary criteria by the panel in addition to standard primary criteria such as scientific excellence and economic impact. Panel members provided feedback regarding the process.

A workshop was convened to gain further feedback and understand wider perspectives on how risk analysis, technology assessment, and engagement could be deployed as a routine part of innovation research activities. Delegates attending the workshop represented a wide range of backgrounds and disciplines, including research council staff, innovation researchers in nanosciences and beyond, social and environmental scientists, regulators and policymakers, and risk practitioners in the insurance sector and beyond. Delegates were asked in groups to undertake a SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis, the results of which are discussed below.

3. RESULTS

All 10 applicants submitted a risk register with their proposal, a typical example of which is shown in the Appendix (the names of the principal investigator, co-investigators, and industrial partners have been removed). All risk registers were completed conservatively, with the overwhelming majority of impacts identified by the applicants being narrowly focused on health impacts associated with exposure to nanomaterials during nanoparticle synthesis, manipulation, and prototype device fabrication. In the majority of cases, the risks associated with these were judged by the applicants as being low or sometimes moderate in nature, with low uncertainty. Feedback from telephone interviews suggested that the rationale for this was that most of the methods and processes to be used were closed or in an aqueous medium with little opportunity for researcher exposure to nanomaterials, and that existing good practice for handling and disposal was sufficient to manage risks (e.g., Environment Agency Advice on Waste Disposal of Nanotubes[26]). In one case the applicants proposed work to evaluate the toxicity of the selected carbon nanotubes as part of the project.

Few potential impacts on the wider natural environment (e.g., associated with eventual device use or end of life) were identified in the risk registers and no future societal impacts were identified at all. This was despite the intention of a number of proposals to develop distributed carbon capture systems for personal domestic fuel generation with significant potential implications. Feedback from the telephone interviews suggested that the risk register was considered a useful tool that provoked awareness of wider impacts (what some described as a "way in" for considering these) and that it was a good approach for managing known potential impacts and associated risks, i.e., those that could be identified with an element of certainty. These tended to be impacts on researchers and technicians associated with laboratory activities in the short to medium term. The risk register alone was considered to be of limited value for identifying unknown and/or unpredictable impacts (e.g., environmental, societal) further along the innovation process (e.g., once the device had been developed, scaled-up, and commercialized), unless other methods that helped identify emerging impacts during that process were continuously interfaced with the risk analysis tool.

A number of applicants realized the limitations of the risk register in this regard, and this was a recurrent theme in both the subsequent telephone interviews and workshop. In response, some applicants costed in work packages or tasks in their proposals that drew on wider disciplines outside the engineering and physical sciences to help with identification of impacts as these emerged. This reflected their awareness of the often unpredictable nature of innovation, its interaction with society, and the need to put in place processes to understand this and feed back into decision making.[27] Technology assessment approaches (e.g., real-time technology assessment, constructive technology assessment,[8,19] and/or life cycle assessment (LCA)[28]) were variously proposed as ways of identifying and understanding impacts on the environment and society for the developing technology and its application in real-time and placing these in the context of a better understanding of the benefits of the emerging innovation. A number of applicants went further to include engagement approaches to understand public and stakeholder attitudes, acceptability, and responses to the emerging innovation. [20,21]

In a number of cases where such wider approaches were included, applicants drew on expertise and strengths in departments outside of chemistry, physics, and engineering in their university. One application, for example, included co-investigators pioneering the embedding of social science, ethical reflexion, and technology assessment (e.g., real-time technology assessment); another (which has been subsequently funded) included a co-investigator from that university's Science and Technology Studies Department, with proposed work in collaboration with their Public Engagement Unit. Others went outside their own university (e.g., an application from one university also included a social scientist as a co-investigator from a different institution with experience in stakeholder and community engagement, requesting budget support for such activities within the project).

4. DISCUSSION

The main objective of this pilot study was to ask applicants to a large innovation research funding call to think about the wider implications of their proposed research early on, and to propose approaches that facilitate reflexion and manage risks and their associated uncertainties. The aim was to embed anticipatory and participatory approaches that do not stifle innovation or encourage low-adventure research, but that underpin high-adventure creativity with responsibility at an early stage. Many of the approaches of qualitative risk analysis, technology assessment, and upstream engagement proposed are far from new, and indeed in the case of technology assessment have a rich history stretching back many decades (see Refs. 8 and 19, and references therein). The novelty in this pilot study was in the embedding of such approaches within a major research funding call, i.e., in an operational context as part of a major research council's funding activity.

Those proposals that were underpinned by a strong commitment to responsible science and innovation were characterized by continuous reflexivity and strong multidisciplinarity, simultaneously deploying a suite of complementary approaches around the proposed innovation research core that included iterative technology assessment coupled to qualitative risk analysis and engagement. By specifically linking this to research funding, this may serve to promote early adaptive management and governance of innovation.[12,15] Researchers were encouraged (and indeed mandated) to think reflexively, to propose mechanisms and recruit expertise across disciplines to help them understand, engage with, and manage the wider implications of their innovation research and development in a more proactive, iterative, and participatory way. Feedback from the telephone interviews with the principal investigators and co-applicants regarding the process revealed that many considered it a worthwhile activity to undertake, with many embracing the philosophy that as scientists they should reflect on the wider implications of their proposed research, a view echoed by the peer reviewers and panelists. One counter view was made that these issues would be best considered by those applying the technology later in development rather than by the scientists themselves.

The approach proposed in this study is complementary to current work that is attempting to enhance reflexivity of scientists in the nanotechnology area and beyond about the wider contexts of their research within a laboratory setting, so-called midstream modulation.[9,16,29,30] This study differs in that the research council mandated scientists to include approaches such as constructive technology assessment[8,31] and risk analysis within the funding proposal itself (i.e., such that they are planned, integrated, and costed activities). Midstream modulation approaches have aimed to demonstrate that research decisions and innovation trajectories can be modulated by engineering and physical scientists themselves by enhancing reflexivity through a number of mechanisms (e.g., by periodically embedding scientists from ethics and social science disciplines in the laboratory setting).[29] Such studies emphasize the need for engagement of scientists from other disciplines with engineers and physical scientists as multidisciplinary teams to support continuous examination of the ethical bases and implications of the research leading to "governance from within." Our study suggests a key role (and indeed responsibility) for those actors who fund innovation research to encourage, and even require, proposals that embed these multidisciplinary ways of working and signposting good practice to facilitate this. This should build capacity within funded projects to support broadening of perspectives, shaping decisions that can lead to modulation of the innovation R&D trajectory in real time. As such, one could conceptualize this as upstream commitment by both research funders and grantees to multidisciplinary activities that facilitate midstream sociotechnological modulation, preparing the ground for this and resourcing it within proposals, accordingly.

Feedback of the study and from the SWOT analysis undertaken during the workshop raised a number of specific areas where more consideration is needed in terms of implementation. One particular consideration is when such approaches should be employed (i.e., consideration of scale): some applicants felt this approach should be applied with every grant proposal submitted. However, resourcing requirements for administering additional peer reviewing would need to be considered in this regard. Others, in contrast, felt that it should be undertaken only for larger thematic programs and Grand Challenges. This was the overall consensus of the workshop, where it was felt that, rather than deployment at the individual project level, an integrated approach should be developed for the larger thematic programs (e.g., energy), and particularly in emerging areas such as geoengineering (for example, solar radiation management or CO_2 removal), synthetic biology (for example, biofuel production), and robotics. This should optimally be defined before the launch of any research call in such areas, with clear mechanisms built in to promote reflexivity and inform decisions regarding innovation trajectories, policy making, and regulation as these co-evolved. This emphasized the need for early engagement and coordination by actors across the TRL framework, supporting integrated approaches, and high-quality multidisciplinary teams.

It was recognized that the approach offered an opportunity to promote a continuously reflexive culture that, when interfaced with risk/benefit analysis and decision making, allowed a measure of adaptive management and governance. It should be noted that management here is referred to in its broadest sense as actions of actors responding to an evolving situation[8] rather than exclusively a regulatory response. However, for this approach to be able to address critical time lags between innovation and regulatory strategy development it was felt important that clear mechanisms were built in to allow an ongoing dialogue that informs and frames policy making (e.g., for this call associated with carbon capture and geoengineering). In this regard there was an important role for institutions that could facilitate an ongoing dialogue with the government and others.

A number of the applicants (particularly those that did not draw on wider expertise in their institutions or beyond) felt out of their depth and wanted more guidance on the sorts of approaches to use and competencies they should draw on (e.g., risk analysis). Most of them recognized that as a culture change it would require guidance for both the scientific and peer-review communities. A view was raised that risk registers might be associated with future liability issues for researchers and that guidance and consideration would be needed in this regard. Researchers would need motivation for addressing risks and support for building interdisciplinary teams with adequately trained researchers from these fields. Raising awareness of appropriate techniques (risk analysis, technology assessment, LCA, engagement), for example, through professional training, and identifying/building institutional capacity to facilitate multidisciplinary proposals was considered important, as was learning from international experiences in the fields of risk analysis, technology assessment, LCA, ethical reflection, and beyond.[29] This would suggest a role for organizations such as the Society for Risk Analysis and others in terms of building such capacity and developing good practice.

There was widespread comment on the need for a consistent and considered peer-review process. Peer review of the risk registers was considered necessary as it was suggested that it would be very unlikely that any applicant to a research call would describe the proposed research as being of high risk and therefore jeopardize funding success. Views were mixed as to whether to include a specific responsible innovation criterion in proposal evaluation. Some felt that if it was not a specific criterion (i.e., a required and evaluated element) it would not be taken seriously while preparing applications. Evaluation by peer reviewers outside the engineering and physical sciences was seen to add value: for example, one proposal involving artificial photosynthesis was mistaken as being "artificial life/synthetic biology" on review and this was helpful for the applicants in terms of ensuring that this confusion was not repeated in the future. It was also considered important to put in place mechanisms to monitor the outputs and impact of the responsible innovation elements of the funded proposals.

5. CONCLUSIONS

Overall feedback indicated that this was considered a useful process, cultural as much as technical, where scientists and those that fund them were encouraged, indeed mandated, to develop an

APPENDIX: SAMPLE RISK REGISTER RECEIVED TO NANOTECHNOLOGIES FUNDING CALL

Risk Register					
Project Activity/ Outcome	Potential Impact	Risk	Uncertainty	Intended Actions/Measures in Place	Who
Synthesis of nanoparticles on RAMSI, lab-scale CHFS.	Health concerns of nanoparticles getting into the air or the environment.	Low	Low	Will follow BSI guidelines for specific disposal plans for nanomaterials, which are based on both U.S. Department of Energy (DOE 2007) and U.K. Environmental Agency Guidance (HWROI) existing documents in all activities herein.	JAD
	CHFS and RAMSI operator exposure.	Low	Low		
Synthesis of iron–sulfur clusters.	Use volatile and smelly thiols.	Low	Low	All reactions will be carried out in well-ventilated fumehoods.	GH
Electrochemical testing of nanoparticle catalysts.	Health concerns of use of nanoparticles for production of electrode array.	Low	Low	Reduce dust hazards for breathing in nanoparticles by handling in well-ventilated fumehoods and use of any protective clothing or measures as recommended by the above guidelines.	KH
Fabrication of electrochemical demonstrator CO_2 treatment.	Health concerns of use of nanoparticles for device fabrication.	Low	Low	Reduce dust hazards for breathing in nanoparticles (these will be dry and highly agglomerated as a result) by handling in well-ventilated fumehoods.	JAD
Synthesis of nanoparticles on the mini-pilot plant.	Health concerns of nanoparticles getting into the air.	Low	Low	See first activity for intended measures: effluent streams will be heavily diluted and we will also use particle traces (ion exchange) to capture particles and as per the above-mentioned BSI guidelines. Any nanowaste will be separated and disposed of separately from regular waste. As per the DOE guidelines, we will evaluate surface contamination or decontaminate equipment used to manufacture or handle nanoparticles before disposing of or reusing it and we will treat wastes (cleaning solutions, etc.) resulting from decontamination as nanomaterial-bearing waste.	JAD
Synthesis of nanoparticles on the mini-pilot plant.	Mini-pilot plant operator safety and exposure, and the environmental impact of the process compared to other routes.	Low	Low	Inherently the process offers low risk. There are, of course, pressure and temperature hazards for supercritical water usage. However, the volume of the pilot plant is much less than a comparable	JAD
		Low	Low	batch scale-up process (ca by 100 times). The pilot plant is also remotely operated and hence safer for operators. The process is also kinder to the environment than many competitor technologies as it uses water as a solvent with the avoidance of toxic organic solvents and offers high product yield, so the process is very atom efficient.	

Note: The process is inherently safer being carried out in water, which reduces the possibilities for air-borne nanomaterials. Any dried nanomaterials will be agglomerated and will be handled in well-ventilated areas or as per the guidelines suggest. Procedures will be put into place in case of small spillages, which can be dealt in the house.

awareness of their wider responsibilities. Embedding iterative risk (and benefit) analysis with technology assessment and public/stakeholder engagement approaches within innovation research proposals was seen as offering a mechanism that considers technical risk issues and associated uncertainties, but that could also provide opportunities for identifying as yet unforeseen effects (economic, societal, and ethical) as these emerge. It may also facilitate upstream engagement with stakeholders and the public as to how these emerging impacts are received. By asking for such considerations in the proposal, applicants were mandated to develop new forms of interdisciplinarity and think reflexively and imaginatively about the potential applications and impacts of their science, with further potential to inform ongoing policy discussions. The opportunity to embed an adaptive learning process into early stage science and innovation was emphasized. A key message that emerged from consultation was the need for an integrated approach within key thematic areas (e.g., on nanosciences, geoengineering, synthetic biology, and robotics) that encourages multidisciplinary proposals that

1. promote continuous reflexivity, participation, and the enhancement of societal learning,
2. embed a set of integrated, multidisciplinary approaches linked to the innovation research core, including technology assessment, risk analysis, benefit analysis, and engagement,
3. provide a continuous feedback process that allows modulation of innovation pathways at specific decision points (e.g., funding at various points in the technology readiness level framework),
4. ensure a clear mechanism for an ongoing dialogue with policymakers as the process coevolves, and
5. thereby embed early on the concept of responsible science and innovation for continuation across the TRL framework.

As such this may serve as an initial translation of the important concepts of adaptive and anticipatory technological governance into operational practice at an early stage in the innovation process. However, at its core, the study raises fundamental philosophical and ethical questions regarding the responsibilities of scientists, funding agencies, and wider society in terms of understanding and managing the wider impacts of science and innovation[32,33] and whether, crucially, such an approach can ultimately "open the door to coresponsibility" in this light.

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