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The IPTS REPORT

EDITED BY THE INSTITUTE FOR PROSPECTIVE TECHNOLOGICAL STUDIES (IPTS)
AND ISSUED IN COOPERATION WITH THE EUROPEAN S&T OBSERVATORY NETWORK

SPECIAL ISSUE: RESEARCH ETHICS AND RTD EVALUATION

EUROPEAN COMMISSION
Joint Research Centre

ENGLISH VERSION

ABOUT THE IPTS REPORT

The IPTS Report is produced on a monthly basis - ten issues a year to be precise, since there are no issues in January and August - by the Institute for Prospective Technological Studies (IPTS) of the Joint Research Centre (JRC) of the European Commission. The IPTS formally collaborates in the production of the IPTS Report with a group of prestigious European institutions, forming with IPTS the European Science and Technology Observatory (ESTO). It also benefits from contributions from other colleagues in the JRC.

The Report is produced simultaneously in four languages (English, French, German and Spanish) by the IPTS. The fact that it is not only available in several languages, but also largely prepared and produced on the Internet's World Wide Web, makes it quite an uncommon undertaking.

The Report publishes articles in numerous areas, maintaining a rough balance between them, and exploiting interdisciplinarity as far as possible. Articles are deemed prospectively relevant if they attempt to explore issues not yet on the policymaker's agenda (but projected to be there sooner or later), or underappreciated aspects of issues already on the policymaker's agenda. The multi-stage drafting and redrafting process, based on a series of interactive consultations with outside experts guarantees quality control.

The first, and possibly most significant indicator, of success is that the Report is being read. The issue 00 (December 1995) had a print run of 2000 copies, in what seemed an optimistic projection at the time. Since then, readership of the paper and electronic versions has far exceeded the 10,000 mark. Feedback, requests for subscriptions, as well as contributions, have come from policymaking (but also academic and private sector) circles not only from various parts of Europe but also from the US, Japan, Australia, Latin America, N. Africa, etc.

We shall continue to endeavour to find the best way of fulfilling the expectations of our quite diverse readership, avoiding oversimplification, as well as encyclopaedic reviews and the inaccessibility of academic journals. The key is to remind ourselves, as well as the readers, that we cannot be all things to all people, that it is important to carve our niche and continue optimally exploring and exploiting it, hoping to illuminate topics under a new, revealing light for the benefit of the readers, in order to prepare them for managing the challenges ahead.

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CONTENTS

EDITORIAL

Ethical Issues in Research Evaluation

Isidoros Karatzas, *Evaluation Unit, DG Research, European Commission* and Stephanie J. Bird, *MIT*

Ethics and evaluation are integral parts of science management and science policy. The current political pressure for public accountability in research and the far-reaching impacts and controversies generated by research (e.g., new technologies, genetics), brought about changes that facilitate increased stakeholder involvement and a possible rapprochement of the scientific community with the general public.

It is of primary importance, before trying to analyse the interface between RTD (Research and Technological Development) ethics and evaluation, to agree on a set of definitions. In the context of this special issue of the IPTS Report, ethics (from the Greek *ethos* meaning custom, mores, character) is taken to define a system of moral principles or values; a principle of right or good behaviour in relating to others; and finally, the rules and standards of conduct binding the members of a profession. Evaluation is a process by which the quality, implementation, target relevance and impacts of RTD activities are investigated, interpreted and examined.

These definitions provide the interface between evaluation and ethics. This interface combines the conduct of research and the ethical assessment of expected results and impact, with three major types of evaluation: accountability, strategic input and in-depth analysis of a specific area. This article by A. Rip lays the foundation for discussion of a "third-generation" ethics, based on the co-evolution of science, technology and society, supported by education and joint learning. It is important that in this context, ethical evaluation does not simply become an additional layer in a bureaucratic process, but stimulates full utilization of existing competencies to produce informed advice as input to decision-making. Essential to this process is that evaluators themselves be trained to recognise the ways in which ethical values are embedded in the design, conduct and reporting of research and evaluation. These values can be more fundamental than the societal values, goals and concerns that motivate the funding of research or influence how its results are used, because embedded values are usually unacknowledged and often unrecognised. The need to support adequate coverage of the ethical issues in evaluation, requires knowledge and expertise that are currently not readily available. Training of "proto-professionals" in this area (interface of ethics and evaluation) is necessary in order not to appear to be treating ethical issues as "add-ons" to the evaluation process.

As self-education and monitoring are important elements of the evaluation process, self-regulation is paramount in the ethical conduct process. G. Toulouse supports the establishment of an evaluation culture as a mechanism for self-regulation in scientific societies. A recent survey by AAAS (American Association for the Advancement of Science) found that 57% of US scientific societies currently engage in or plan to engage in

activities to promote research integrity[1]. The same survey shows that, at present, there has been very little formal evaluation of the effectiveness of these initiatives, and considers that rigorous evaluation is essential in order for the scientists and the public to have confidence in the self-regulatory functions of the scientific societies. Evaluation methodologies and self-regulation codes of conduct should be seen as living processes, evolving and adapting to the changes in the environment, and openly discussed in order to benefit from varying experiences and interdisciplinary approaches. If the scientific community does not take a leading role in safeguarding good research practices, it is probable that non-scientist stakeholders will undertake this task.

In a participatory democracy, public confidence in government research activities is also greatly dependent on accountability. Scientists and research managers who follow the day-to-day development of research and witness the benefits of scientific inquiry, are convinced that these activities are valuable. This intuitive conclusion is difficult to quantify in a meaningful way and may not be easily communicated to all stakeholders[2]. Political demands for the quantification of research results and impact catalysed a shift in the values and ethical context of research evaluation. S. Cozzens' article analyses this shift as it was shaped by implementation of GPRA (Government Performance and Results Act). In the new context, the evaluator is responsible not only to his/ her professional community and his/her clients, but also to other stakeholders: strategic planners, policy makers and especially the public at large. In this new role, the evaluator seeks a clear articulation and measurement of public benefit.

Stakeholder involvement is sought in order to improve the effectiveness of policies. In P. Thompson's article, the process which highlights the input from research to policy is outlined using, as a case study, the food and agricultural biotechnology area. Rapid advances in this field have led to new interpretations of long-standing policies in food safety, environmental impact and animal health. The shifting ethical paradigm presented in S. Cozzens' paper is also apparent here: ethical bias can be hidden within evaluation methodology itself and through socio-economic impact assessment and risk quantification, can affect policy choices. Furthermore, as Thompson points out any evaluation of socio-economic impacts of RTD will be incomplete if it fails to recognise the potential for new technologies (e.g. biotechnology) to affect the fundamental nature of the world in ways that alter basic legal concepts (such as property rights). As a result, evaluation must also address the possibility of restructuring at the constitutional level.

As in agricultural biotechnology, the restructuring seems necessary and long overdue in the area of gene technology and ethics. The paper by D. Ibaretta and A-K. Bock presents the third type of evaluation dealing with an in-depth analysis of a field. In this context, the evaluation and ethics interface contains issues relating to safeguarding good scientific practice, and the use and impacts of research results. The ethical assessment of research should then be carried out at three levels[3]. According to the opinion of the European Group on Ethics (EGE) these levels are:

- the research project from the point of view of the modalities of implementation;
- the declared aims of the research and the envisaged applications of the results; and
- the possible uses and consequences, in the medium and long-term, of the results and their impact on individuals, the environment and society in general.

Evaluation of the first two levels is currently undertaken in the EC Quality of Life Programme as outlined in the brief note by L. Cordier.

Concerning the third level, the EGE opinion outlines the necessity for stakeholder involvement: "the ethical assessment is up against the complexity and unforseeability of all the possible uses and consequences of the results of research. This is all the more difficult in that it is bound up with conceptions of the future of society in general. This ethical assessment is, therefore, more a subject for public debate and for national and Community socio-political bodies". In the third level, the ERA (European Research Area) initiative[4] proposes specific themes for action (ERA point 7, Area of Shared Values), including:

- Organization of "Citizens' Conferences" at European level;
- Strengthening of links between national and European ethics committees;
- Opening up of national ethics committees to experts from other European countries; and
- Comparison of criteria used in the national and European programmes with the prospect of convergence around common principles, while respecting diversity.

The success of stakeholder involvement and the effectiveness of public debates will greatly depend on a number of important structural changes. Firstly, ethics and evaluation should be part of university curricula, sensitizing future researchers to the challenges they will face later in their careers. As R. Hollander argues in her note, this training should be extended to the teaching staff so that relevant codes of ethics become familiar.

A second important change requires increased effort to improve communication with the stakeholders. This communication depends on a common language and a basic shared understanding which will require effort by scientists, educators and science journalists, as well as the stakeholders to bridge conceptual gaps. Poor communication of the actual science, coupled with a lack of scepticism on the part of the public, contributes to potential misapplication or abuse of science[5]. Moreover in order to critically evaluate research findings that are used to influence or support public policy, it is important:

- To be aware that values are embedded in scientific research
- To understand the ways in which values become part of science and
- To be able to distinguish the nature and source of values in scientific studies

The openness of the scientific community to discuss issues of their expertise with their colleagues and the stakeholders, plus the value shift of the role of the evaluators towards an extended audience, will bring about the necessary structural changes and facilitate the co-evolution of science, technology and society.

Notes/References

1. E. Dumez, The Role and Activities of Scientific Societies in Promoting Research Integrity, Professional Ethics Report, Volume XIII, Number 3, Summer 2000 (**http://www.aaas.org/spp/dspp/sfrl/per/per/htm**).

2. A.N. Link and J.T. Scott, Evaluation of Technology-based Institutions, Kluwer Academic Publishers, 1998.

3. Opinion N° 10, Group of the European Group on Ethics (EGE), "The Ethical Aspects of the 5th Research Framework Programme", available in **http://www.europea.eu.int/comm/secretariat-general/sgc/ethics**

4. Towards a European Research Area, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, January 2000.

5. J.M. Garrett and S.J. Bird: Ethical Issues in Communicating Science, Editorial Overview, Science and Engineering Ethics, Volume 6, Issue 4, 2000.

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Ethics, RTD and Evaluation

Arie Rip, *University of Twente*

Issue: Ethical aspects are increasingly being invoked as important for society's assessment of new scientific and technological developments. RTD (Research and Technological Development) evaluations which not only address the management of programmes and the extent to which goals are achieved, but also consider impacts, should attempt to evaluate what has come to be called ELSI (Ethical, Legal, and Social Implications).

Relevance: It is not immediately obvious how RTD evaluators can handle ethical aspects. A better understanding of ethics in relation to RTD, and to scientific and technological developments more generally, is an essential precondition.

Ethics tends to be viewed primarily as a force acting in the name of humanity against the supposedly autonomous dynamics of scientific and technological developments

Introduction[1]

The key step to incorporating ethical aspects in the evaluation of new scientific and technological developments is to get away from the prevailing, but misguided notion that ethics is a countervailing force, acting in the name of humanity, against the supposedly autonomous dynamics of scientific and technological developments. This conceptualization automatically gives the moral high ground to the opponents of a particular new development (for example, modern biotechnology), while proponents defend themselves in terms of a general promise of progress to be realized.[2] Controversies about new technologies reproduce this pattern. Proponents see resistance and attribute it to ignorance and emotions, while critics argue that it is not just promised performance, but also the societal relevance or need that should be evaluated. We can perhaps have square tomatoes, which are easier to harvest by machines – but do we need them? This is the debate about the so-called "fourth hurdle", in recent biotechnology, but the point can be generalized: even if assessed as safe, the question of real societal advantage should be considered. In biotechnology, and for new developments in the life sciences related to genetics, reproduction, and modification of human life, there is now a "fifth hurdle": the impact on human values. Ethics is then called upon explicitly, as an ally. The ease with which the metaphor of "hurdles" is used shows the prevalence of a proponent-opponent storyline, and ethics is, almost by definition, on the side of the opponents.

Second and third generation ethics

One effect of the one-sided association of ethics with defence against new technology is the neglect of the ethical and socio-political aspects of how scientists and technologists continually (and positively) add to the "furniture" of our world. Philosophical reflection on this shaping of

our world is sorely needed. A related effect of the proponent-opponent storyline is the way it locks scientists and technologists into insider roles, where they define what is good for society in terms of their own limited projections. An intriguing example is the development of cochlear implants, which would give deaf people some hearing. The deaf community, however, saw this as undermining their way of life, and making them into second-class hearers, rather than having their own way of communication.[3]

The current use of the terms "ethics" and "ethical aspects" is part of the problem, rather than a pointer towards a solution. Firstly, there is the confusion between ethics as a scholarly discipline and actual morality, values and work towards what might be called the "good life". Scholars in ethics analyse moral issues, but need not themselves hold or propound high moral values. Their contribution can be important, but not in the sense that they themselves are exemplary in taking moral positions.

Legal and political debate and analysis, and the general questions of a "good" social order are important normative issues, which are not served by treating them as ethical issues. Seen from the perspective of impacts, new scientific and technological developments are open, often unstructured societal experiments, in which many actors with various perspectives participate, often without their consent. These are much larger

ended character of this co-evolution, rather than immediately trying to attribute praise and blame. In our knowledge society, which is also a risk society, reflection is possible, and competencies in such reflections can be and should be encouraged. For Hronszky, this means that ethics, in its third-generational form, is endogenized, as an integral part of the co-evolutionary dynamics. Actors other than professional ethicists and spokespersons for moral values would also be important, and RTD evaluators could play a role as well.

Part of the notion of third-generation ethics is not to start by defining a moral high ground, but to discover it through a joint learning process. This approach is similar to recent developments in technology assessment (independent from the recent interest in ethical aspects).[4] The co-evolution and learning perspective mitigates the danger of over-simplified reference to given moral and societal norms and values, which would lead to fundamentalism, and in our present pluralistic societies, to mutual condemnation. But there is also the other danger of accepting anything and everything, and containing variety only through procedures (voting –and abiding by the outcome– being one example).

An important strand of second-generation ethics is cultural relativism. From this viewpoint, debates about ethical impacts come to be seen as cultural issues, to be resolved by mutual accommodation and/or compartmentalization.

One effect of the one-sided association of ethics with defence against new technology is the neglect of the ethical and socio-political aspects of how scientists and technologists continually add to the furniture of our world

Ethical studies and moral debate tend to put values and individual choice up front, rather than reflecting on social order and the "good life" in our scientific-technological and risk society

with its focus on individual values

At a European Workshop on Socio-Economic Impact Evaluation in Seville, November 2000, the Hungarian philosopher of science and technology Imre Hronszky called for a "third generation" of ethics. His starting point was the co-evolution of science, technology and society, and the joint learning that is possible if one recognizes the open-ended character of this co-evolution.

debates around biotechnology. Issues of standing, of scoping and agenda-building, and of style of interaction then take precedence over substantial

learning process. This approach is similar to recent developments in technology assessment

issues. The focus is on what constitutes a good debate, a good decision-making process, a good interaction. Questions about what constitutes a "good" life in our late-modern, technological and risk society can be addressed, but that is up to the participants.

We need to build on the insights of second-generation ethics and take a further step, whether we call it third-generation ethics or not. That is, in addition to procedural ethics and mediation and other attempts at conflict resolution, we should be concerned about division of responsibilities, which is a way to address social order and the good life without fully specifying what they should be. This is particularly important for the co-evolution of science, technology and society and how these processes can be modulated.

An important strand of second-generation ethics is cultural relativism. From this viewpoint, debates about ethical impacts come to be seen as cultural issues, to be resolved by mutual accommodation and/or compartmentalization

There has been a traditional division of responsibility in which scientists and technologists produced new options, industrialists took them up, and society had to take care of the impacts

The division of responsibilities is no longer acceptable. Scientists are now expected to anticipate impacts and foresee risks

Sharing responsibility

Impacts are co-produced, but responsibilities for impacts differ. The ambivalences are brought out well in Jerry Ravetz's aphorism: "Science takes credit for penicillin, but society takes the blame for the bomb." In general, one can speak of a division of responsibility, in the same way we speak of a division of labour in production, making up the social order. The traditional division of responsibility was that scientists and technologists produced new options, industrialists took them up, and society had to take care of the impacts, somehow. The 1933 World Fair in Chicago celebrated a century of progress, and took as its motto: "Science Finds – Industry Applies – Man Conforms."

This division of responsibilities is no longer accepted for two reasons. First, anticipation of impacts is now expected (witness the rise of technology assessment), regulatory agencies are more pro-active, and actors, including scientists, can be criticized for not being concerned with possible impacts. The action of molecular biologists in the early 1970s to call attention to possible dangers of recombinant-DNA research, and to consider a moratorium on such research, was an important event, and set a precedent. Second, there are the new, and newly recognized, risks of long-term and often uncertain, but possibly considerable consequences of human activities, for example of low-level exposure to chemicals and radiation. Such new risks haave not been adequately addressed, because no one is responsible for them. But they are now recognized, by the public, policy-makers, scientists, and even insurance companies, and there are attempts to define new responsibilities.

The precautionary principle[5] is one possible guideline in addressing new risks and one could look upon it as a macro-ethical stance. Its political, legal and economic aspects have been debated, and there is now some acceptance of it, at least in Europe. The responsibilities involved are larger than the drafting of regulations, however. It must be linked with the general idea that scientists are responsible for early warning, even if this is based on necessarily speculative theories and models. It is also linked with the recognition of the importance of interaction with old and new stakeholders and various publics.

What we see here is an emerging "constitution" for our technological risk society. This is a *de facto* constitution in that it is not laid down by law, although elements may eventually find their way into laws and regulations. It can nevertheless be forceful in guiding action, just as cultural norms and values in all walks of life are forceful. Appraisal of such an emerging constitution is important, and social and political philosophy can make an important contribution.

With this is in mind it will be clear that including ethical aspects in RTD evaluation is not just

a matter of adding a further kind of impact, namely an impact on moral and cultural values. A variety of issues are involved, ranging from integrity of scientific research (as it is called in the USA) to societal debate, always against the backdrop of the broader issues of the co-evolution of science, technology and society. In this broader picture, RTD evaluation can be framed as the question how actual and emerging divisions of responsibilities –as part of the social order– work out. If a division of responsibilities has become more or less articulated, or if it is specified as a goal, evaluators can check how well things have actually turned out. If not, they can still identify and assess what is happening in terms of evolving divisions of responsibilities. In both cases, their work helps to increase reflexivity in our late-modern societies.

This is a process approach, and has not place in debates about the importance of one or another value. For some issues, there is general acceptance. For example the requirement of informed consent and the protection of privacy. In these cases RTD evaluators can check whether the rules were followed. Other issues are still open, and sometimes contested. Such questions can also be taken up in an RTD evaluation, but at arm's length. As it were in "boxes", where actors (directly or as reported by the evaluator) can have their say without their values being endorsed by the evaluator (other than identifying them as sufficiently important to be mentioned).

The substantial task that the evaluator can address is an appraisal of the evolving division of responsibilities. The current interest in science and governance supports the inclusion of such a task, and identifies important elements such as interaction with stakeholders and citizens.

Conclusions

As with the established interest in dissemination of research results and interaction with users of research, evaluators work on two levels: i) the actual tracing of dissemination, uptake by users, satisfaction, and ii) a general understanding of such interactions and roles which allows sensible collection of data and interpretation of what they mean. Such an understanding builds on professional competencies and experience. For the new task, competencies and experience may not yet be in place. Hiring an ethicist or a political philosopher as part of the evaluation team, however, is not an answer (or at best, only a small part of it). Given the recent interest of sociologists and political scientists in issues concerning the knowledge society and the risk society, and in interactive policy making, their competencies could play an important role. Many professional RTD evaluators have, in fact, a background in these scholarly fields.

The evaluation of ethical impacts will stimulate a reflexive co-evolution of science, technology and society. Evaluators will then not only be professionals who do a good job, but also intellectuals who are motivated by the possibility of contributing to the "good life".

Including ethical aspects in RTD evaluation is not just a matter of adding a further kind of impact, namely an impact on moral and cultural values, into the equation

The substantial task that the evaluator can address is an appraisal of the evolving division of responsibilities. The current interest in science and governance supports the inclusion of such a task, and identifies important elements such as interaction with stakeholders and citizens

Keywords

evaluation, ELSI, co-evolution, third-generation ethics, division of responsibilities, impact assessment

Notes & References

1. I am grateful to Barend van der Meulen (University of Twente) for his helpful comments.

2. The pervasiveness of this storyline is visible in how the European Group on Ethics, set up by the European Commission, defines its task as: reflecting before we descend on slippery slopes, so that progress will remain in harmony with fundamental societal values. This is an (unauthorized) quote from Marja Sorsa's presentation of the work of the European Group on Ethics, at the Workshop on Socio-Economic Impact Evaluation, Helsinki, 26-27 November 1999.

3. Garud, R., and Ahlstrom, D., *Technology assessment: a socio-cognitive perspective*, Journal of Engineering and Technology Management 14, 1997 pp 25-48.

4. Grin, J., and van de Graaf, H., *Technology Assessment as Learning*, Science, Technology and Human Values, 21, 1996 pp 72-99; Schot, J., and Rip, A., *The Past and Future of Constructive Technology Assessment*, Technological Forecasting and Social Change 54, 1997 pp 251-268.

5. For more information on the precautionary principle see:
http://europa.eu.int/comm/off/com/health_consumer/precaution.htm

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Evaluation in Science: an Antidote to Impunity

Gérard Toulouse, *Ecole Normale Supérieure*

Issue: Mastery of science, the integrity of the individual scientist, and the governance of scientific institutions, are three inter-related domains which are open to ethical appraisal. Experience shows that a culture of impunity tends to develop whenever structures or groups of people are left above or beyond evaluation.

Relevance: Full advantage should be taken of existing or potential opportunities for the exchange of experience on ethics-related evaluation issues among academic institutions. This, however, must be accompanied by the fostering of a broader culture of evaluation.

Introduction: shared knowledge

It is necessary to recognize that even within the restricted circles of the European scientific community a better quality of understanding between scientists remains desirable. In order to establish a corpus of common knowledge on which meaningful social debates and relevant actions can be based, the resources of scientific organizations within civil society (e.g. associations for the advancement of science) are also clearly important, and they should be strengthened at the European level. Moreover, "Ethics and RTD evaluation" is a central theme for the construction of a European Research Area[1] and in order to be properly addressed, much effort will be required at many different levels, including all levels of education. Within this larger background picture, this article, within the limitations of space, focuses on a few topical issues about which pragmatic steps can be proposed.

Against the culture of impunity

It is because the 20th century has been so marked by contrasts, with an unbounded capacity for creation, and an equally boundless capacity for destruction, that the 21st century, drawing lessons from the past, will be the century of ethics, said French President Jacques Chirac. The 21st century may well come to be also considered the century of evaluation. It should be noted that the word "evaluation" contains the word "value", and for science it is important to remember that this should include moral values as well as others, such as economic values, costs, returns, etc. In retrospect, it seems clear that the emphasis on scientific objectivity and the moral neutrality of science was, consciously or unconsciously, self-serving (Garrett and Bird, 2000). The claim that science is intrinsically innocent, and all the blame for evil consequences should be directed toward technical applications, is part of an attempt to draw a circle of perfect

The claim that science is intrinsically morally neutral, and all the blame for evil consequences should be directed toward technical applications, is part of an attempt by the scientific establishment to draw a circle of perfect impunity around itself

The expression "culture of evaluation" is meant to imply an extension of individual assessment tasks into a broader ensemble, encompassing other relevant dimensions of the scientific enterprise

impunity around itself. Academic freedom and social responsibility go hand in hand.

Towards a culture of evaluation

Many scientists still ask: "Why has ethics become so fashionable nowadays in science?" Whereas the right question to ask should be: "Why were ethical considerations excluded for so long from scientific activities?" Indeed the time is ripe for innovation, emulation and international cooperation on ethics. We live in a period of transition in which a dynamic equilibrium has yet to be found, given that the advances of science and technology constantly raise novel problems. Along the way, it undoubtedly will be necessary to develop antidotes against possible abuses and perversions of ethics –there are parodies of ethics, just as there are parodies of justice, parodies of democracy, etc.

One frequent objection is that ethical judgement in science is extremely difficult. It is indeed true that ethics is often concerned with conflicts of values and rationales, and hard dilemmas may be met. But science is not easy either; yet we manage to do it because we take it seriously. So the right question is not whether collective ethical reflection in science is easy, but whether we take it seriously.

Finally, it must be readily admitted that ethics committees alone will not solve all problems; their action must be part of a broader culture of evaluation.

The expression "culture of evaluation" is meant to imply an extension of individual assessment tasks (e.g. journal refereeing) into a broader ensemble, encompassing other relevant dimensions of the scientific enterprise: the professional values and ethical standards of both the individual and the community, lessons drawn from past and experience from elsewhere, review of evaluation procedures, etc. Such an evaluation culture will evolve and mature, guided by an increasing awareness of the full scope of the social responsibilities of the scientific community.

Transition to a culture of evaluation implies reciprocal shifts in attitudes among both evaluators and those being evaluated. Ideally, evaluation will cease to be feared and resisted. Rather it will be recognized and sought after as an aid to the evolution of science.

The scope of ethical appraisal

Broadly speaking, three domains are open to ethical appraisal:

- Mastery of science: bounds and tempo (relative speed of progress on various research frontiers);
- Professional integrity of scientists (e.g. developing a scientific ethos which is unfavourable to misconduct, dubious practices, etc.);
- Scientific institutions (governance, evaluation, collective responsibilities).

The last item is no less relevant than the previous ones, but it is a domain in which there is considerable inertia.

In 1997 two convergent reports were independently issued, one on *Ethics and scientific institutions* by the French *Comité d'éthique pour les sciences* (CNRS, 1997), the other on *Safeguarding good scientific practice* by the German Commissison on Professional Self-Regulation (DFG, 1997). Both illustrate the close overlap between ethics and evaluation, including the evaluation of and by scientific institutions: *What is necessary (...) is that not only every individual scientist and scholar, but especially the institutions of science - universities, research institutes, learned societies, scientific journals, funding organizations - develop a consciousness of good scientific practice and apply it in their day-to-day activity.*

Sixteen detailed recommendations are listed in the German report, covering topics such as mentorship, authorship, referees, funding, evaluation criteria, protecting whistleblowers, disclosure of conflicts of interest, treatment of allegations of misconduct, etc. The European Science Foundation is currently working on the definition of a set of European standards (a European code of good scientific practice) based on the range of national experiences.

Every university, institution of higher learning, research institute, scholarly society, and science academy should have an ethics committee, properly informed of what is being done at different levels: local, national, European, global (cf. UNESCO's World Commission on the Ethics of Scientific Knowledge and Technology –COMEST). This would make it possible for individual scientists to be able to turn to a local ethics committee, in order to obtain adequate help and advice if needed. The composition of these committees should be balanced between disciplines, genders, ages and hierarchical positions and include not only scientists, but also laypersons such as journalists, artists and representatives of the associative sector. In the near future, temporary service in an ethics committee will be part and parcel of any scientific career. This spread of responsibilities is imperative in order to dispel concerns that a new caste of non-scientists will dictate what constitutes the responsible conduct of science.

One country with concrete initiatives in the area of ethics is Norway. It has a set of national ethics committees, a programme of double doctoral training in science and ethics, a parliament-sponsored Commission on human values and a complex of institutions associated with the Nobel Institute of Peace. This offers a potential model for other countries which are confronted with similar issues.

Concrete steps

The 1999 Budapest World Conference on Science for the 21st Century (the first such international gathering since the Vienna conference in 1979), which was convened by UNESCO (United Nations Educational, Scientific and Cultural Organization) and ICSU (International Council for Science), achieved consensus on three major points: the importance of ethics in science; on the urgent need to recognize the important contributions and role of women in science; and, on new opportunities for increased cooperation between the natural and social sciences. Many debates revolved around the gap between developed and developing countries (UNESCO, 1999), schematically referred to as the "North-South divide". In this regard, a noteworthy element was the influence of the Third World Academy of Sciences (TWAS), which did not exist at the time of the Vienna conference (the TWAS was created by Abdus Salam in 1983).

In May 2000, the InterAcademy Panel on International Issues (IAP, comprising 80 academies of science) endorsed a suggestion by Bruce Alberts, president of the NAS (National Academy of Sciences, USA), to create an InterAcademy Council (IAC), modelled on the National Research Council, which has been the operating arm of the NAS for over eighty years. The purpose of the IAC will be "to facilitate the provision of advice and recommendations on issues of global importance for those organizations and governments formally requesting such an input".

The IAC is of particular interest both because it is a new international organization that will be responsible for assessment, and because its creation may test the credibility of science academies as evaluators, since many of them, living on a legacy of prestige or power, are prone to resist any evaluative control over their own modes of operation.

Every university, institution of higher learning, research institute, scholarly society, and science academy should have an ethics committee so that individual scientists can always obtain adequate advice if necessary

One outcome of the Budapest conference on science for the 21st century was the creation of an InterAcademy Council (IAC) to facilitate the provision of advice and recommendations on issues of global importance

If some IAC reports prove able to prevent misguided or premature ventures, and to act as a sobering influence against the recurrent hubris of various military, industrial and political complexes, this new advisory council will indeed serve an important purpose. Furthermore, the parity between North and South academies, which has been instituted within the IAC structure, is also in itself a significant move, and a step forward in ethical terms.

As frequently occurs in scientific matters, this initiative brings both risks and opportunities. Among the risks is that the most powerful players come to dominate the smaller ones (no doubt, some political and corporate interests expect that the weaker academies will be easily manipulated). In this regard a key question is whether ethical concerns will be rejected out-of-hand, in the name of strict "scientific objectivity", or whether they will receive adequate attention. A crucial debate, moreover, will take place around the concept of the precautionary principle[2].

In order to meet these new challenges, pressure will increase for the renovation of the national science academies in Europe. It is to be hoped that the recent developments concerning the IAP and IAC will provide a decisive push for reform, so that all national science academies within Europe will become truly credible partners (Toulouse, 1998; 1999). If European science has the legitimate ambition to be able to stand up and to speak up convincingly on the world stage, a thorough process of internal reform is a prerequisite.

The provisions contained in the European Research Area initiative provide a useful framework in this regard. It is to be hoped that full advantage will be taken of these opportunities, especially with regard to the exchange of experience and the possibility of cross-participation in relevant articles.

About the author

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Keywords

evaluation, ethics, scientific institutions, academies, UNESCO, responsibilities, impunity cultures, culture of evaluation, education

Notes

1. Towards a European Research Area, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, January 2000.
2. For more information on the precautionary principle see:
http://europa.eu.int/comm/off/com/health_consumer/precaution.htm

References

- UNESCO documentation concerning the Budapest World Conference for Science (1999) is available on the Website: **http://www.unesco.org/science/wcs**
- Toulouse, G., *Regards sur l'éthique des sciences,* Paris, Hachette-Littératures, 1998.
- Toulouse, G., *Ethics enters the 21st Century,* Physics World, p. 13-14, November 1999; *The Century of Evaluation,* Europhysics News, p. 127-129, November/December 1999.
- Garrett, J.M., and Bird, S.S., *Ethical issues in communicating sciences,* Science and Engineering Ethics 6 436-442, 2000.
- CNRS, *Ethics and scientific institutions,* Les Cahiers du Comets, June 1997, available at **http://www.cnrs.fr**
- DFG, *Proposals for safeguarding good scientific practice,* Weinheim, Wiley-VCH, 1998; also available at **http://www.dfg.de**

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Results Oriented Management: A New Ethical Context for Research Evaluation

Susan E. Cozzens, *Georgia Institute of Technology*

Issue: Over the last decade there has been a sea change in research evaluation, leading to greater emphasis on results-oriented management. This shift has stimulated much comment from the technical viewpoint, but little from an ethical viewpoint.

Relevance: As applied to research, the methodological elements of results-oriented management are not new. However, old methods are being combined in different ways, with different potential uses and implications for policy.

Introduction

The Government Performance and Results Act of 1993 (GPRA) required all U.S. government agencies to write strategic plans and to set and report on annual performance targets using quantitative indicators. Similar legislation was put into effect during the 1980s and 1990s in a number of parliamentary systems, including Canada, New Zealand, Sweden, and the United Kingdom. Elements of the results-oriented approach have been incorporated into research evaluation in the European Union, and some close cousins have been adopted for university assessment in several countries.

Research evaluators, like all evaluators, carry responsibilities in three dimensions. First, they are responsible to their clients –to produce usable results–, next, to their professional communities –to produce competent results–, and finally, they are responsible to the public –to produce and share a growing base of knowledge about how government programmes work, including questions about whether and how they are serving the public interest. In the pre-GPRA configuration it was possible for U.S. research evaluators to be highly responsible to their clients and to their professional communities, but difficult for them to serve the public. Because of the emphasis on results and the requirement for stakeholder consultation, however, the new framework gives evaluators new opportunities in this respect.

Old systems

In the pre-GPRA era, two different styles of research management had been established in federal agencies in the United States, one targeted and one untargeted. They were differentiated first and foremost by the specificity of their technical objectives. In energy research, for example, specific new technical options were explored. In agriculture, the aim was to improve farming practice. Such areas were often subject to formal

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Research evaluators are responsible to their clients, their professional communities and to the public. The new emphasis on stakeholder consultation after GRPA has created new opportunities for evaluators to fulfil their roles

planning processes, and programme officers were responsible for demonstrating on a regular basis that the research supported was contributing to the objective. If it was not, the programme was changed to make it more likely to be effective.

In contrast, at the National Institutes of Health (NIH), the goal was to advance fundamental understanding of biological processes underlying human health. Programmes supported fields of research that were relevant to medical problems, but seldom tried to press specific solutions. At the National Science Foundation (NSF), the untargeted approach went even further. The NSF sought to maintain the health of academic research, and supported excellent research in almost any field that needed fundamental explorations to balance mission-supported efforts. Both these agencies developed strong systems to let the research community itself determine which projects to fund through a strong peer review system.

In the pre-GRPA era targeted and untargeted styles of research management coexisted. Targeted areas such as energy and agriculture pursued specific goals, whereas health research sought to advance fundamental understanding of biological processes

Responsibility to the public presented the greatest challenge for all the pre-GPRA research evaluators. The specialized expertise of the research community has effectively protected it from close scrutiny, and the theory that underlies peer review tends to devalue assessments of completed research

These two styles of management also developed distinctive programme evaluation practices, to fit the theory underlying their operations. Before the 1990s, the fundamental research agencies commissioned occasional formal programme evaluations, primarily outside their core research activities. For example, the NIH carried out extensive data collection on its training programmes, and took a careful look at its international exchanges. The NSF evaluated centres, women's programmes, and the exploratory research efforts. Mission agencies, like the Department of Defense and the Department of Energy, by and large had systems of regular programme review, in which outside evaluators were asked to provide an assessment of programmes based on information provided by the agency.

Old roles

Three professional communities were involved in these pre-GPRA evaluations. The first were evaluation staff, who were most often former researchers who took on management responsibility after some time in government as research administrators. Second were the members of the research community who were recruited for evaluation panels. Third were the professional evaluators, mostly non-academic contract research organizations plus a handful of academic researchers and small firms.

The lines of responsibility from all three of these evaluator groups to agency management have been clear. Evaluation staff and contract researchers had to negotiate permission and resources from senior management for everything they did. The questions senior management wanted to have answered were the natural focus, and there was little room for experimentation. As for external reviewers, their independent judgement was valued and protected in the process. Agencies therefore tried to choose reviewers that understood their mission and context, so that any advice they received would stay on track.

In the second area of responsibility, i.e. that to the professional community, the three groups diverged. Staff and reviewers were both particularly tied to the research community. The scientific competence and judgement they brought to the process were highly valued. The professional evaluators, while not researchers in the fields being evaluated, nonetheless had the standards of their own methods communities to answer to. They needed to be systematic and unbiased in the collection and presentation of evidence, to use the best methods available, etc. Since the research assessment community is quite small, and contracts are very competitive, the quality control exercised through reputation is fairly strong.

The third area of responsibility, i.e. to the public, presented the greatest challenge for all the pre-GPRA research evaluators. The challenge

began with the insulation of research programmes themselves from high levels of public attention. The specialized expertise of the research community has effectively protected it from close scrutiny, especially since the voting public is usually either neutral or positive in its views about research. Second, the theory that underlies peer review tends to devalue evaluations of completed research. There are no objectives in the traditional sense against which a basic research programme should be evaluated. Some evaluation staff therefore claimed in the pre-GPRA era that no one knew how to evaluate such a programme. Finally, the gradual narrowing of the performer base for research evaluations to the contract research organizations reduced the incentive to build a broader base of knowledge about how the research enterprise works. The result was that there was very little in the way of an empirically based discussion around alternative research policies.

New systems

The new accountability systems are distinguished by the need to be explicit about many matters that were implicit under the old system. The concept of excellence itself must be spelled out and made visible outside the research community. Because the new system stresses value to the public, research evaluators are moving away from their close relationship with the research community and toward a clearer articulation and measurement of public benefit. Four emphases in these new frameworks work toward that end: results, indicators, stakeholder involvement, and strategic planning.

Results. The new accountability systems demand that results be shown for money spent. Excellence involves producing something tangible and specific. For government laboratories and other targeted programmes, attention to results is part of their normal business. Regular progress reports provide information to management on what is coming out of the activities of the lab. Programme review uses that information to inform future activities. For the fundamental research programmes, however, the new demand for results is revolutionary. It is remarkable how little was known about the results of grants before this new movement, and equally remarkable how little the information that was available was used in management. The NSF can serve as an example. This lack of concern with results was the flip side of the emphasis on maintaining excellence through competitive proposals and project selection through peer review. The NSF was very confident that what it had funded was the best available. This was fine under the old system for accountability. But under the new expectations, including those outlined in GPRA, that confidence was not enough. The agency needed to show outputs and outcomes, not just a high level of quality control on inputs.

Indicators. A second emphasis in the new accountability systems is the use of quantitative indicators. If the worth of a programme cannot be measured, so the philosophy goes, the programme itself cannot be managed. In the U.S., GPRA forced a critical examination of the numbers that were candidates for performance indicators. What were available were many kinds of input numbers, measuring levels of activity as they appear in management information systems. In fact, most of the indicators in most performance monitoring systems around the world are input indicators, derived from management information systems that pre-date accountability requirements.

In the area of results indicators, publications could have been used as an output indicator. Not a single U.S. agency has chosen to do so. The U.S. university system has steered away from the use of publication counts as an evaluative measure, because it encourages quantity rather than quality.

The new accountability systems are distinguished by the need to be explicit about many matters that were implicit under the old system. The four areas of emphasis are results, indicators, stakeholder involvement, and strategic planning

Most of the indicators used in performance monitoring systems are input indicators. Among the possible output indicators, publication statistics, in particular, are avoided, given their tendency to place emphasis on quantity rather than quality

The NSF consciously chose not to base performance goals on output measures because of the possibility for distortion of behaviour.

In the end, then, quantitative outcome measures – what GPRA seeks – are rare in the performance reporting of U.S. research agencies, and appear primarily in the programmes at the technological end of the spectrum. Applied research agencies have been able to do technological road-mapping of the paths toward their targets, and report on passing the milestones on the roadmap. Economic cost-benefit analysis appears in the report of the standards laboratories of the National Institute of Standards and Technology. Similarly, improvement toward specific technical targets is reported, for example, increasing the power of instrumentation in facilities provided by the Department of Energy.

Stakeholder involvement. The new accountability systems require stakeholder involvement. Excellence is no longer found only in the views of managers and the research community. Representative democracy has required that participatory democracy play a role. Excellence is now in the eye of many beholders, all of whom report back to legislators on what they see.

A role for external stakeholders had been growing in the research enterprise for some time before the new accountability systems were put in place. The first set of stakeholders welcomed into the system were from industry, through cooperative programmes and centres; and they are still the numerically most dominant group. The new accountability systems have encouraged a generalization of stakeholder involvement, however, beyond industry. In the U.S., for example, state and local governments are often brought into the decision processes around research, and sometimes schools are as well. NGOs are also becoming frequent participants in these processes, for example, when environmental groups participated in the U.K. Foresight exercise. When government laboratories and funding programmes develop the knowledge base for regulatory decisions, it is important to include users from government departments in the research management process.

Strategic planning. Last, but by no means least, the new accountability systems require strategic planning. Many government organizations had not done this before, and quickly discovered the challenges of trying to make sense of the miscellany of functions they had been given by legislatures over the years. In the U.S., applied research organizations, including most government laboratories, have responded well to this demand and developed and refined long and short-term strategic goals that are being translated effectively into performance goals. For example, the National Oceanographic and Atmospheric Administration has performance goals for improving the lead-time and accuracy of predictions of severe weather conditions. For example, they want to increase the lead time in predicting flash floods from 41 minutes to 57 minutes, and increase accuracy to 85%. These goals are of obvious benefit to the public, and give a clear target for organizing research efforts.

There is still a great deal of ambivalence in the research community about the value of strategic planning, especially in fundamental research, where there is general agreement that roadmaps are not possible. Yet there are positive results from the process. First, it has sharpened understanding of goals and audiences, even in basic research programmes. Strategic plans do this by introducing a refined language of goals, and making it part of discussion in the everyday life of the organization. The first teams to use the new system at the NSF were forced into a serious discussion of who the audience was for the field (beyond the researchers

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themselves), and the best ways to reach that audience. Before GPRA, such teams would have been taken up with an audit of the project selection process, and never asked about either audiences or results.

Second, strategic planning is transforming basic research into strategic research. There is a (possibly apocryphal) quotation about basic research from Werner von Braun: "Basic research is what I'm doing when I don't know what I'm doing." There is no room under the new accountability systems not to know what you are doing. Even basic research needs its public justification. At the NSF, for example, we discovered under GPRA why we were supporting astronomy: kids get excited about science through astronomy, and getting kids excited about science is good for the country. Surely, this process of specification is good for the enterprise.

New roles and responsibilities

While the evaluator's responsibilities to clients, professional communities, and the public have changed under this system, the three groups are still involved, and in somewhat similar relationships to one another. However, the key change is that some new groups are also included, and a much broader and higher level of attention to their input is required.

The new groups include the stakeholders for the programmes (who must be involved in the strategic planning process under the terms of the Act) and the Congressional audience. These two groups represent the public in ways that are significantly stronger than the delegation patterns of the old systems. They form an active audience for results from the assessment system, an audience that goes above the heads of the senior agency management who were the primary clients before. Those agency heads are still an important part of the picture, but now they do assessment by requirement, not just by choice, and the assessment results must be reported outside the agency in the form of performance indicators.

The policy and planning staff who commissioned special evaluation studies in the old system and organized external review panels are still active and central players under the new systems, but budget offices have become an important group of partners and clients in the enterprise, and policy and planning staff have the added responsibility of getting programme staff from across their agencies to "buy in" to the system adopted. Adding all these additional players has made the lives of planning and policy offices much more complicated.

Many research agencies have looked to peer review processes to address the GPRA puzzle. The review panels are thus still involved, and in fact play a more central role in the new systems because their results have a Congressional as well as agency audience. They must make judgements that can be publicly available, and they know that their judgements can have an impact on resources for the agency that has chosen them. From the agency viewpoint, the panel solution fits the ideology of peer review, and invokes the established protection of "special expertise" that insulated research for so long from close public scrutiny. However, there is an underlying issue that has barely been broached in the discussion around the use of peer panels for GPRA: conflict of interest. The conflict of interest problem is solved in project selection processes by having an individual with a conflict on a specific proposal leave the room while it is discussed. However, the conflicts of interest in programme evaluation run much more broadly and deeply than the narrower rules acknowledge or address. Almost everyone who is likely to be technically competent to serve on a panel at research programme level also has a stake in seeing the field supported.

Although strategic planning is clearly difficult to apply to fundamental research given the lack of concrete goals, positive results have nevertheless been obtained from the process

Many research agencies have looked to peer review processes to address the GPRA puzzle. The review panels are thus still involved, and in fact play a more central role in the new systems because their results have a Congressional as well as agency audience

Finally, while in theory GPRA could have provided an increased level of activity for professional evaluators, in practice, at least in research, it has not. The law assumes that agencies are engaged in regular programme evaluation, and requires that agencies provide a schedule of their programme evaluation activities. But designing an indicators system is quite a different task intellectually than designing a good programme evaluation, and agencies have been taken up with the difficulties and costs of GPRA implementation over the last five years or so.

Ultimately, the work that will be generated for professional evaluators under GPRA will come from its incorporation into standard practices within the many parts of agencies. Agencies will need help with involving stakeholders in strategic planning, developing a model of the logic of their programmes, and translating new concepts of outputs and outcomes into measures. The new role for professional evaluators is to facilitate those processes, rather than to carry out set-piece evaluations. This move makes it easier for the professional evaluator to be responsive to the three groups indicated earlier. The client is closer, and more directly involved in absorbing the results of the process, so the results feed more directly into his or her decision making. As with the earlier set of skills, a professional community of evaluators sets the standards for quality in this work. Finally, because stakeholders are more closely involved, there can be a greater sense of direct public responsibility.

Agencies will need help with involving stakeholders in strategic planning, developing a model of the logic of their programmes, and translating new concepts of outputs and outcomes into measures

Conclusions

In summary, then, the new approach stresses the responsibility to provide value to the public. As a result, the new environment has produced a new configuration of roles and responsibilities for the groups involved in the research evaluation process. Research evaluators are moving away from their close relationship with the research community and toward a clearer articulation and measurement of public benefit. The professional evaluator can no longer sit in an office, setting up and carrying out pristine research designs and writing elegant reports that may or may not get read. Instead, the new research evaluator needs a new set of skills, like facilitating strategic planning, which helps organizations articulate their goals; stakeholder involvement, which reaffirms the role of the public; and logic modelling, to clarify how programmes bring about their results. Knowledge of methods is still necessary since the model of programme logic will ultimately need to be translated into indicators, in an efficient way that speaks in simple language to non-experts. Yet the new world also calls for better knowledge of management practices and issues, and a greater sensitivity to the Congressional context for a programme.

This new context holds significantly more promise for allowing issues of public service and public interest to surface in the assessment process, on a case by case basis. If the potential of GPRA for achieving this change is fulfilled, it will have lived up to its name and indeed achieved results.

Keywords

results, evaluation, ethics

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References

- Assessing Fundamental Science: A Report from the Subcommittee on Research, Committee on Fundamental Science, National Science and Technology Council. July 1996.
- Cozzens, S. E., *Results and Responsibility: Science, Society, and GPRA.* In AAAS Science and Technology Policy Yearbook, 1999, edited by A. H. Teich, S. D. Nelson, C. McEnaney, and T, M. Drake, Washington, DC: AAAS.
- Evaluating Federal Research Programs: Research and the Government Performance and Results Act. National Academy Press, 1999.
- Wholey, J., and Hatry, H., *The Case for Performance Monitoring,* Public Administration Review, November/December (Vol. 52, No. 6), 1992 pp. 604-610.

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Food and Agricultural Biotechnology: Ethical Issues Behind Research Policy Choices

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Issue: Food and agricultural biotechnologies have demanded new interpretations of longstanding policies in food safety, environmental impact and animal health. The controversy over agricultural biotechnology reveals a number of ethical concerns in existing approaches to agricultural research evaluation.

Relevance: Ethical issues might be raised with respect to many types of technology. An overview of the controversies associated with agricultural biotechnology provides a microcosm for understanding a key set of ethical issues associated with any attempt to evaluate research and technology development, or to use such evaluations in research management policies.

The agricultural sciences present a particularly interesting case study for examining ethical issues in technology evaluation, and especially so with respect to the products of gene transfer

Introduction

An important issue in science today is the tension between research policy, which stresses optimal trade-off of risk and benefit, and policy that aims to satisfy criteria of informed consent. A second major issue concerns the role of agency and intention in making research choices, and questions of responsibility for both intended and unforeseen consequences. A third concerns the appropriate role of uncertainty and precaution in research evaluation and planning. A fourth concerns the socio-economic impact of agricultural biotechnology on the viability of farms, rural communities and the process of globalization.

The agricultural sciences present a particularly interesting case study for examining ethical issues in technology evaluation, and especially so with respect to the products of gene transfer. Worldwide, agricultural research has been organized and conducted by public institutions such as national and international research centres and government funded university scientists for over 100 years. Agricultural research has, from the outset, been highly applied, aimed at discoveries and technology development that would lead to improvements both in food and fibre production, and in rural quality of life. Furthermore, agricultural technology and its socio-economic effects have been extensively studied by social scientists for many decades. Although this research has not been undertaken within the framework of officially mandated evaluation activities, it has been conducted in a variety of national settings, has deployed many social science research methods, and has examined a wide range of issues.

Given this knowledge base, research administrators approached the development of new agricultural and food technologies using techniques for mapping and transferring genes from one organism to another with a high degree of confidence in their ability to prospectively select appropriate topics for research. Given the controversy and chaos that greeted the products of food and agricultural biotechnology, it is apparent that their confidence was somewhat misplaced. Neglect of ethical issues, both in the evaluation of agricultural research and in the policy decision making that was based on the social science literature extant in the 1980s when many key decisions were made, is one of the key elements in accounting for this failure.

Agricultural science and technology evaluation

As noted, agricultural science and technology have been subjected to social impact evaluation for several decades. This research is based on economic simulation models developed primarily for monitoring and predicting price and quantity performance of the agricultural sector for both developed and developing country economies. Many agricultural technologies lend themselves to estimation of impact on commodity yields, and data on farmer adoption rates and reported yields allow these estimates to be incorporated into agricultural sector models. Beginning in the 1960s, these basic models began to be augmented with techniques to evaluate negative externalities attributable to environmental impact and social dislocation. A number of the key papers in this literature are collected by Berardi and Geisler (1984).

Beyond this sketch, the evaluation literature on agricultural science is too broad to summarize in this context. Vernon Ruttan's book *Agricultural Research Policy* (1985) provides an overview, and Rossmiller's *Agricultural Sector Planning* (1978) describes an interdisciplinary methodology for identifying research needs and implementing a participatory system for continuous evaluation of research impact. More recent publications by Huffman and Evenson (1993) and the U.S. Department of Agriculture Economic Research Service (1995) update this literature. Johnson and Bonnen's *Social Science Agricultural Agendas and Strategies* (1991) collects essays by many of the world's leading agricultural researchers summarizing what is known and what needs have yet to be met regarding the evaluation of agricultural and food systems performance.

Existing agricultural sector models provide a number of ways for analysts to disaggregate the various influences on system performance, and to make defensible judgements about the relative influence of various contributing causes, including scientific and technological innovation. Given some plausible assumptions, models designed to predict agricultural sector performance with respect to commodity prices and environmental externalities can serve as a basis for technology evaluation. First, one must assume that under the conditions of competitive markets, gains to agricultural producers *or* to food consumers (in the form of lower food prices) represent beneficial outcomes. Second, one must assume that it is possible to compare such beneficial outcomes with negative outcomes in a manner that adequately reflects all the parameters that are relevant to the evaluation process. Despite the initial plausibility of these assumptions the experience with agricultural biotechnology reveals several areas of weakness.

First, economic and sociological methods in use prior to 1980 were almost exclusively focused on a utilitarian or consequentialist model of technology evaluation, and provided decision makers with little insight into the way that science and technology could raise ethical issues relating to

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Despite their intuitive plausibility, models designed to predict agricultural sector performance suffer from a number of weaknesses arising, in particular, from their exclusive focus on a utilitarian or consequentialist model of technology evaluation

Utilitarian or consequentialist thinking sees scientific research and technology development as an initiating event that causes a variety of more or less quantifiable effects

rights and consent. This problem became particularly evident with respect to the way that consumer interests were neglected in evaluating the use of rDNA techniques to produce genetically modified (GM) foods. Second, these methods were so strongly focused on outcomes that they neglected the way that the motives and moral character of actors would be used to evaluate the acceptability of products and the credibility of information regarding biotechnology.

A third weakness concerns the environmental risks of genetically engineered crops, and a fourth involves the effect of genetic engineering on the socio-economic structure of farming and rural communities. These two weaknesses are surprising in that social science research on agricultural innovation provided ample reason to expect that environmental impact and social consequences would be sources of controversy. One might conclude that decision-makers simply ignored the lessons from previous evaluations of agricultural technology. On the contrary, however, with respect to both environmental and social consequences, the way in which evaluation information is conceptualized can presuppose a particular ethical orientation. The current social controversy over agricultural biotechnology can be traced to a somewhat narrow way of understanding the ethical significance of the evaluation process (Thompson, 1997a).

Optimization vs. consent

Prior to 1980, virtually all of the social science research on the evaluation of agricultural research had an implicit ethical orientation toward what philosophers would characterize as *utilitarian* or *consequentialist* thinking. In this model, scientific research and technology development is implicitly understood as an initiating event that causes a variety of effects on human, animal and environmental health, the economic well-being of individuals, and on aggregate socio-economic indicators such as GDP, distribution of income, national budgets, balance of payments and the like (Thompson, Ellis and Stout, 1991). As Barré (1999) points out, the methodological challenges in modelling the complex social mechanisms that mediate this causality, and in measuring these impacts, can be overwhelming. However, in this context, it is more important to highlight the normative presumptions involved in this conceptualization of evaluation.

The key idea is that each impact of research, as characterized above, can be understood as having beneficial or detrimental effects on social or individual welfare. Investments in science and technology should promote beneficial impacts. Given the likelihood that there will be few instances of unalloyed benefits, research administrators should be sure that benefits outweigh detrimental outcomes, and should regard research investment as a process of seeking the best possible ratio of beneficial to detrimental outcomes. This norm is commonly expressed in terms of seeking the best ratio of benefit to cost. It derives from John Stuart Mill's statement of *the utilitarian maxim*, which states that the action that is ethically justified is the one that achieves "the greatest good for the greatest number."

Agricultural biotechnology was subjected to a great deal of prospective evaluation research using a decision model suggested by the utilitarian maxim. Milton Hallberg (1992) produced a volume of essays reviewing the extensive evaluation literature on just one product of biotechnology, recombinant bovine somatotropin. Since risks to food consumers were judged to be very small, and benefits in the form of lower food prices were estimated to be significant, the acceptability of biotechnology to food consumers was never taken to be an important criterion in *ex ante* evaluations. As is now well documented, however, even con-

sumers who expressed interest in trying GM foods were deeply resentful of a marketing approach that denied them the opportunity to give or withhold consent. Even consumers who thought of themselves as potentially benefiting from GM foods nevertheless insisted upon the right to decide for themselves whether to eat them or not (see Durant, Bauer and Gaskell, 1998).

This should be seen as an ethical flaw not in the sense that anyone in agricultural research planning or evaluation wilfully acted unethically. Instead, the utilitarian orientation of the model being used to conceptualize the evaluation process had blind spots with respect to issues of coercion, consent and rights. The weakness of utilitarian thinking with respect to such issues has been recognized for many years. Although it may be possible to adapt consequence-evaluating social science research models to more accurately reflect the importance of consent and rights, it may be easier to conceptualize the issues of rights and consent as distinct elements of the evaluation process. That is, in addition to evaluating the causal effects of a research programme, evaluators should ask how the research (or its expected products) could affect the rights held by affected parties prior to the implementation of a new technology. If rights will be affected, the burden on research administrators is to make a good faith effort to secure the participation and consent of affected parties, *rather* than simply to convince themselves that the expected benefits of the research outweigh its costs (see Thompson 1997b; 2000).

Intentions, interests and motives

A second weakness of standard utilitarian research evaluation is that in looking so intently at the future consequences of a research activity, it tends to neglect the past. However, in the ethical evaluation of human action, the things that lead up to an action can be much more important than the consequences that follow it. In particular, the intentions, interests and motives of the agents who perform actions make all the difference in deciding whether certain acts are right or wrong. One act of pulling the trigger may be heroic or forgivable while another is murderous, and an analysis of the consequences involved in either case may not be particularly sensitive to the difference between the two.

With respect to agricultural biotechnology in the 1980s and 1990s, the primary actors appear to have been positioning themselves to control and dominate research on seeds and agricultural technology well into the future. Certainly the commercial firms such as Monsanto, Novartis and Dupont have expected to profit from their research activities, but there have been arguments that their activities extend well beyond simple profit seeking into more extensive attempts to control the food and agricultural system. Furthermore, while one expects commercially funded research to meet the test of profit, the new agricultural biotechnologies have been accompanied by a growing recognition of the way that profit-seeking motivations may affect research policy in the publicly governed research sector, too. These developments may have undermined the credibility of key actors in the agricultural biotechnology arena.

Barré (1999) calls for more descriptive attention to the networks of actors involved in research and development, and agricultural biotechnology may provide a case in point. With a few exceptions, agricultural research evaluation conducted prior to 1980 was largely inattentive to the interests, intentions and motives of actors. Even when it was attentive, it was infrequently integrated into prospective evaluations of agricultural biotechnology in a manner that would have helped research administrators appreciate the way in which evolving industry-public sector research relation-

The premise of utilitarianism is to act so as to achieve the greatest good for the greatest number. From this point of view investments in science and technology should promote beneficial impacts whilst minimizing negative ones

The utilitarian model used to conceptualize the evaluation process failed to foresee public resistance to agricultural biotechnology because of its blind spots with respect to issues of coercion, consent and rights

ships might compromise the acceptability of the technology in the future. As with respect to consent, the reason for this is at least arguably to be found in the limitations owing to the utilitarian bias of the primary social science instruments for conducting and communicating the evaluation of agricultural research.

Environmental risks of agricultural biotechnology

The environmental consequences of agricultural biotechnology have been hotly contested ever since the first field tests for genetically engineered ice-nucleating bacteria were proposed in the early 1980s. As such, research administrators, planners and evaluators could not have overlooked the need to assess environmental impact. Furthermore, the utilitarian approach to evaluation of research is certainly capable of incorporating evaluation of environmental impact. Although the technical specification of environmental risk can become quite complex, risk is treated as an expected value in most utilitarian or consequential approaches to evaluation. Under the expected value approach, detrimental outcomes are evaluated probabilistically, and the risk of a technology is rendered as a function of probability and degree of harm.

A second weakness of standard utilitarian research evaluation is that it fails to take into account intentions, interests and motives. Thus it failed to foresee the negative impact of the public's perception of the primary actors as seeking to control and dominate research on seeds and agricultural technology

Although the utilitarian approach is able to incorporate an evaluation of environmental impact, the fact that the benefits of reducing environmental risks are public goods means standard markets do not provide incentives for reducing them

The expected value interpretation of risk suggests two related strategies for coping with the unintended environmental consequences of technology. One is to treat risks conceptually as forms of cost, which are then subjected to cost-benefit style optimizing. In one sense there is nothing unique about environmental consequences, since in standard cost-benefit analysis virtually all costs *and* benefits are probabilistic in nature and are modelled for evaluation as expected values. However, environmental costs *are* thought to exhibit characteristics that make them differ from straightforward costs borne directly by producers and consumers in that benefits of reducing environmental risks and costs are public goods. As such, standard markets do not provide incentives for reducing environmental risks and costs.

The upshot is that when risks are interpreted as expected values, unintended environmental consequences are understood as regulatory problems. Government regulatory agencies evaluate environmental impact and regulate markets so that public benefits of reduced pollution and environmental damage are realized. This general approach was accepted by both public and private research entities undertaking product development of agricultural biotechnologies in the 1980s and into the early 1990s (Bosin, 1990; Townsend, 1993). However, the evaluation of environmental risk was also conceptualized as an essentially technical activity, rather than one in which ethics would play a role. In this respect, the utilitarian presumptions of the prevailing approach to agricultural research and technology assessment may have led decision makers astray. By 1999, public confidence in regulators' ability to address environmental risks of agricultural biotechnology had fallen considerably (Durant, Bauer and Gaskell, 1998).

The underlying ethical issue concerns the appropriate standard to apply in evaluating possible environmental impact. In moving immediately to a characterization of risk in terms of probability and degree of environmental harm, the expected value orientation of the utilitarian evaluation model militates against a precautionary mode of decision making. In the precautionary model, uncertainties are given precedence over what is known about possible benefits and costs; environmental risk is not characterized in terms of known potential outcomes and their measured probability of occurrence. In comparison with a predilection for choosing the optimal trade-off between cost and benefit, the precautionary stance is considerably more open-ended. As an approach to evaluation, it takes pains to present evaluative information in a

way that does not lead the audience to presume that known risks should be the basis for decision, rather than unknown risks. In doing so, it leaves open the possibility that a non-comparative, non-optimizing criterion for addressing environmental impact may be the appropriate one for decision-makers to use in a given situation (Ticknor, 1999).

Social consequences of agricultural biotechnology

Based on robust studies of previous agricultural technologies, social scientists were quick to predict that agricultural biotechnology would be a contributing factor in the restructuring of agriculture, the continuing decline of small-scale family-operated farms, and the concentration of economic power among a few agribusiness firms (Kalter, 1985; Kloppenburg, 1985; Kenny, 1986). These predictions precipitated several years of heated debate in the United States, mostly focused on the acceptability of social consequences associated with recombinant bovine somatotropin. Some argued that benefits to consumers counterbalance social costs incurred by farmers and rural communities (Tweeten, 1991). Others argued that these social consequences should be regulated in much the same ways as public health and environmental impact (Lacy and Busch, 1991). The issue was effectively decided in the United States when a 1994 executive report concluded: "At no time in the past has the Federal Government prevented a technology from being adopted on the basis of socio-economic factors," (U.S. Executive Office of the President, 1994, pp. 35-6).

There is an implicit ethical orientation to the U.S. Government's approach to social consequences. It is that social consequence debates revolve around the issue of distributing the costs and benefits of biotechnology. By not intervening in market mechanisms that influence producers' decisions to adopt or reject technology, U.S. Government policy permits the productive resources to be allocated according to market forces governing capital investments. Ethical and political debate about the distribution of wealth in society is then focused on redistributive tax policy and entitlement programmes. It is difficult for government agencies to manipulate complex capital investment and producer decision making in a predictable fashion, and since private firms make these decisions, the public interest in the outcome of producer decision making may not be immediately obvious. In contrast, taxation and entitlements are debated in a political forum that is more obviously related to distributive justice. Furthermore, the U. S. consensus predilection for capitalism over centralized planning in the production sectors of the economy militates strongly in favour of this approach.

This argument would be persuasive were it not for the fact that technological innovations can result not only in restructuring that reflects production efficiencies and the distribution of wealth, but also in a transformation of capabilities that is equivalent to a redefinition of basic constitutional rights, (Winner, 1983). The system of property rights in effect at any given time reflects a social and legal consensus on rules for access, control, exchange and the right to profit from use of goods, but it also reflects basic physical and biological capabilities with respect to the goods in question. Legal systems of property rights include stipulations about the right to transport portable goods, for example, but not for parcels of land or bodies of water because these are, by their very nature, permanent fixtures of a given landscape. However, technological innovations in biotechnology have effectively disaggregated traits (such as specific plant or animal characteristics or in the case of the so-called Terminator gene, biological reproductive capacity itself) so dramatically as to have vitiated property rights that farmers would have once held in seeds or animal

In moving immediately to a characterization of risk in terms of probability and degree of environmental harm, the expected value orientation of the utilitarian evaluation model militates against a precautionary mode of decision making

By leaving the market to decide the acceptance of a technology, U.S. Government policy permits the productive resources to be allocated according to market forces governing capital investments. Ethical and political debate about the distribution of wealth in society is then focused on redistributive tax policy and entitlement programmes

breeding stock. As such, it is doubtful that the old social consensus on rules for property exchange and capital investment in agricultural production can simply be carried over into a post-biotechnology world without opportunity for renegotiations and political debate (see Kloppenburg, 1988).

Clearly, the economic, political and sociological issues that would bear on such a debate are complex, and any adequate discussion of them is far beyond the scope of the present article. The relevant point is simply that evaluation of socio-economic consequences of science and technology will be incomplete if it fails to address the possibility of restructuring at the constitutional level. This is, arguably, a point that has either been overlooked or repressed in the last decade of debate over the social consequences of agricultural biotechnology.

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Conclusion

Perhaps the most obvious need for ethics in the evaluation of socio-economic impact from scientific research and technological innovation is simply that scientific integrity demands a fair and truthful evaluation process. To casual observers, it may seem as if ethical evaluation demands little more than rigour and honesty on the part of evaluators. However, the case of agricultural biotechnology indicates that there are a number of ways in which ethical bias can be hidden within evaluation methodology itself. Even those analysts who strive assiduously for objectivity can produce evaluation studies that fail to identify issues where the end products of scientific innovation create problems with respect to individual consent, or the intentions and conduct of key actors. Methodologies that presume a particular approach to the quantification of risk may neglect or conceal ethical issues that emerge when a precautionary approach is seen as the alternative to risk-benefit trade-off optimization. Assessment methodologies may also conceal the deeper significance of socio-economic consequences when they are represented solely as issues in distributive justice.

Keywords

food and agriculture biotechnology, research evaluation, research policy choices, risk, social impact

References

- Barré, R., *Public research programmes: Socio-economic impact assessment and user needs. The IPTS Report* 40 (Dec.):5-9, 1999.
- Berardi, G. M., and Geisler, C.C., Eds. *The Social Consequences and Challenges of New Agricultural Technologies.* Boulder, CO: Westview Press, 1985.
- Bosin, M., *Policymakers address biotechnology: Issues and responsibilities.* In D. J. Webber, Ed. *Biotechnology: Assessing Social Impacts and Policy Implications.* Westport, CT: Greenwood Press, Pp 167-180, 1990.
- Durant, J., Bauer, M.W., and Gaskell, G., Eds. *Biotechnology in the Public Sphere: A European Sourcebook.* London: The Science Museum, 1998.
- Hallberg, M., Ed. *Bovine Somatotropin and Emerging Issues.* Boulder, CO: Westview Press, 1992.
- Huffman, W. E., and Evenson, R., *Science for Agriculture: A Long Term Perspective.* Ames, IA: Iowa State University Press, 1993.
- Johnson, Glenn L. and Bonnen, J.T. *Social Science Agricultural Agendas and Strategies.* East Lansing, MI: Michigan State University Press, 1991.

- Kalter, R., *The new biotech agriculture: unforeseen economic consequences,* Issues in Science and Technology 13:125-133, 1985.
- Kenny, M., *Biotechnology: The University-Industrial Complex.* New Haven, CT: Yale University Press, 1986.
- Kloppenburg, J. Jr., *The social impacts of biogenic technology in agriculture: Past and future,* In G. M., Berardi and C. C., Geisler, Eds. *The Social Consequences and Challenges of New Agricultural Technologies.* Boulder, CO: Westview Press, Pp. 291-321, 1985.
- Kloppenburg, J. Jr., *First the Seed: The Political Economy of Plant Technology: 1492-2000.* Cambridge: Cambridge University Press, 1988.
- Lacy, W., and Busch, L., *The fourth criterion: Social and economic impacts of agricultural biotechnology,* In J.F. MacDonald, Ed. *Agricultural Biotechnology at the Crossroads: Biological, Social and Institutional Concerns.* Ithaca, NY: National Agricultural Biotechnology Council, 1991.
- Rossmiller, G. E., *Agricultural Sector Planning — A General System Simulation Approach.* East Lansing, MI: Michigan State University Press, 1978.
- Ruttan, Vernon., *Agricultural Research Policy.* Minneapolis: U. Minnesota Press, 1985.
- Thompson, Paul B., (1997a) *Food Biotechnology in Ethical Perspective.* London and New York: Chapman and Hall Aspen Publishing, 1997.
- Thompson, Paul B., (1997b). *Food Biotechnology's Challenge to Cultural Integrity and Individual Consent,* Hastings Center Report, 27(4): 1997, pp 34-38.
- Thompson Paul B., *Agricultural biotechnology, ethics, risk and individual consent,* Encyclopedia of Ethical, Legal, and Policy Issues in Biotechnology New York: Wiley, 2000.
- Thompson, P. B., Lain, Ellis G., and Stout, B.A., *Values in the agricultural laboratory,* In P. B. Thompson and B. A. Stout, Eds. *Beyond the Large Farm: Ethics and Research Goals for Agriculture* Boulder, CO: Westview Press, 1991, pp. 3-32.
- Ticknor, Joel A., *A map toward precautionary decision making,* In C. Raffensparger and J. Ticknor, Eds. *Protecting Public Health and the Environment: Implementing the Precautionary Principle.* Washington, DC: Island Press, 1999, pp 162-186.
- Townsend, R., APHIS and agricultural research, In R. D. Weaver, Ed. *U.S. Agricultural Research: Strategic Challenges and Opportunities.* Bethesda, MD: Agricultural Research Institute, 1993, pp. 141-154.
- Tweeten, L., *The costs and benefits of bGH will be distributed fairly,* The Journal of Agricultural and Environmental Ethics 4: 1991, pp108-120.
- United States Department of Agriculture Economic Research Service. *Agricultural Research and development: Public and private investments under alternative markets and institutions.* Staff Paper 9517. Washington, DC: USDA, 1995.
- United States Executive Office of the President. *Use of Bovine Somatotropin (BST) in the United States: Its Potential Effects – A Study Conducted by the Executive Branch of the Federal Government.* Washington, DC: Government Printing Office, 1994.
- Winner, L., *Techné and politea: the technological constitution of society.* In P. T. Durbin and F. Rapp, Eds. *Philosophy and Technology* Dordrecht: D. Reidel, 1983, pp. 97-111.

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Medical Uses of Gene Technology: Ethical and Social Concerns

Dolores Ibarreta and Anne-Katrin Bock, *IPTS*

Issue: Advances in the field of biotechnology are making it possible to determine and manipulate some of the genetic material of human cells for medical purposes. The Human Genome Project has opened a wider door to these possibilities, providing scientists with the data and tools needed to identify and understand the basis of genetic diseases and disorders, together with other inherited traits, while also foreshadowing difficult ethical controversies.

Relevance: Within the European Union ethical issues concerning the application of the growing knowledge of human genetics are being approached differently from one country to another according to the different philosophical and moral attitudes in the Member States. Since the future application of gene technology in medicine will concern every citizen in Europe, these topics have to be discussed in a way that involves the public to ensure transparency and trust in political decisions. More so as the development of a common view on ethical issues throughout Europe might be necessary. The design of a European Research Area includes an "area of shared values" and recognizes as well the need to further the dialogue between science and society.

Developments in genetic research and gene technology have elucidated possible genetic causes of known hereditary diseases and have made it possible to diagnose and influence a person's genetic makeup

Introduction

Apart from environmental factors, it is a person's genome (the entire genetic material that is present in each cell of the body) that determines his/her health and susceptibility to diseases. The genetic material of an individual is contained in the nucleus of each cell in the form of chromosomes (46 chromosomes in 23 pairs, each set derived from one parent). The chromosomes contain the genetic material, the DNA, which consists of 4 different building blocks, the nucleotide bases. The sequence of these nucleotide bases within the DNA molecule constitutes the genetic information. The sequence that codes for one single protein is called a gene. The human genome consists of around 3 billion bases and approximately 100,000 genes. Changes in the number and structure of chromosomes can lead to severe disorders, but small changes in the sequence of the nucleotide bases can also cause disease.

Developments in genetic research and gene technology have elucidated possible genetic causes of known hereditary diseases and have made it possible to diagnose and influence a person's genetic makeup. The main areas of application of gene technology for medical use are genetic testing

(for diagnostic purposes), gene therapy at somatic and germ cell level and, most recently discussed, the therapeutic cloning of embryo stem cells for developing specialized tissue.

Genetic testing

The analysis of structural chromosome aberrations, which for example cause Down's syndrome (3 copies of chromosome 21 instead of 2), is well known and has been in use since the 1960s (cytogenic investigations). The rapid progress in molecular genetics and the development of new techniques has made possible the *direct* analysis of the DNA and the development of tests for mutations in genes which might be responsible for certain diseases as cystic fibrosis, Huntington's disease and sickle-cell anaemia, and also for arthritis and cancer, which are clearly influenced additionally by environmental factors. The ongoing Human Genome Project will provide more information on the underlying genetic causes of several diseases and will push the development of respective tests.

Genetic tests have a number of actual and potential uses:

- Broadening the diagnostic repertoire to detect or verify the cause of unclear symptoms (e.g. cystic fibrosis, Huntington's disease).

- Predicting possible future onsets of diseases. **Prenatal diagnosis** includes cytogenic analysis and molecular genetic testing of the foetus. The first is routinely applied in the case of pregnancies in older women. Chromosomes are examined for microscopically visible macromolecular aberrations. Molecular genetic tests are used to determine whether the embryo carries certain mutations within a gene that are responsible for hereditary diseases. In the case of *in vitro* fertilization the early embryonic cells can be examined via preimplantation diagnosis before the embryo is implanted into the uterus. **Preclinical diagnosis** is applied after birth before any symptoms of a hereditary disease are recognizable. Persons can be tested for carrying genetic mutations and thus information obtained about future health. **Predisposition diagnosis** can be used to determine the personal risk for certain multifactorial diseases like, for example, coronary heart disease. Persons affected will be able to change their lifestyle according to the diagnosis and thus reduce their risk of developing the disease. These and other tests will be developed in the future, building on the expanding knowledge of the human genome.

- Customizing medical treatment for each patient. Some patients may not respond to drugs to which others respond very well, or even have adverse reactions to these treatments. Pharmacogenomical research is trying to correlate the genetic makeup of individuals with their response to different medicines. The aim is to find "the right medicine for the right patient" to make treatment more effective in future.

Today genetic tests are available for about 100 hereditary diseases. These tests are mainly used for predictive, i.e. prenatal or presymptomatic, purposes. The information obtained differs in many ways from conventional diagnostic tests, thus raising new issues.

Quality of genetic tests

Because of the far-reaching consequences of genetic test results, the quality of genetic testing services and the reliability of the results are fundamental prerequisites for the application of this technique. Genetic testing is becoming increasingly frequent, tests being offered not only by specialized hospitals but also by analytical laboratories and these tests are sometimes offered directly to the patient. Currently, there are no

The rapid progress in molecular genetics and the development of new techniques has made possible the direct analysis of the DNA and the development of tests for mutations in genes which might be responsible for certain diseases

Genetic testing may be applied to embryos to determine whether they carry genetic mutations, and to adults to determine their predisposition to certain diseases or suitability for certain types of treatment

common European regulations ensuring minimum standards of the services provided (e.g. in terms of technical equipment, technical training of laboratory staff, accurate interpretation of results and provision of sufficient information to users, reliability of the results, and pre- and postanalytic counselling (Dequeker & Cassiman, 1998)).

Recognizing the need to ensure test quality and consumer protection concerning genetic testing on a European level, the IPTS organized a workshop in July 2000 with all the main stakeholders to discuss possible ways of achieving this. Additionally the OECD is active in fostering appropriate and harmonized approaches for dealing with genetic testing on an international level.

There are as yet no European quality standards specifically for genetic tests

Ethical aspects of genetic testing

Genetic testing can raise ethical concerns, particularly when it is used as the basis for embryo selection, or if tests are able to show a predisposition for a disease for which there is no cure

In the case of prenatal testing the question of sparing children from future suffering because of a severe hereditary disease has to be weighed against the question as to whether we, as a society, have the right to decide which lives are worth living. In the case of preimplantation diagnostics the possibility of choosing between different embryos arises and with it the possibility of abuse and "positive eugenics" (selecting the gender and in future perhaps certain characteristics to get a "quality child"). The ability to select embryos according to their genotype might in the future create social pressure on parents who have disabled or ill children ("nowadays this is avoidable and therefore it should not happen") and a changing acceptance for handicapped persons.

Another ethical question connected with preimplantation diagnostics is the use of totipotent embryo cells for a biopsy and embryo selection. This technique destroys these cells, which have the potential to develop into human beings and are thus regarded as having the same status as embryos, which have to be protected. Preimplantation diagnosis is not allowed in Germany, Portugal, Austria and Switzerland.

A person's knowing that they carry the genes for a hereditary disease, which will perhaps not show its first symptoms within the next 10 or 20 years, is a heavy psychological burden, even more so when there is no expectation of therapy. On the other hand, this knowledge can enable the affected person to arrange the remaining period of his/her healthy life accordingly. In contrast to conventional diagnosis, the genetic test result not only affects the person tested, but also family members, who could carry the respective gene(s) too and who may or may not want to have any information about their risk of future disease.

With the possibility of predicting potential risks of suffering from a disease in the future, the question of ownership and confidentiality/accessibility of genetic data arises. Especially in the context of health insurance and employment there is a danger of discrimination. Insurance companies might refuse to sell life or health insurance to high-risk individuals or charge much higher premiums. On the other hand, people who can provide proof of a clean genetic history can be offered much cheaper contracts. However insurance companies themselves might also experience problems if there is no obligation to disclose risk factors for genetic disease. For instance, people who know that they will develop a serious disease could buy extra insurance cover, whereas people who know they have only a small risk could decide to buy less insurance. This distortion would drive up premiums and could undermine the health insurance market. To counter this risk, in October 2000 insurance companies in Great Britain obtained permission to ask for genetic tests results. So far, the Department of Health's genetics and insurance committee has approved only a test for Huntington's disease, but others will certainly follow. In

contrast, in most other countries the use of genetic information by insurers is restricted or even prohibited.

As regards the effects of genetic testing on the job market, employers prefer workers who are less likely to become ill, because this reduces the costs of replacement and retraining, interruptions in production and insurance. Moreover, some work environments may be known to predispose workers to a high rate of certain illnesses, and employers might prefer to hire workers who are genetically resistant rather than susceptible to these particular environment-related illnesses. Employers might hire only those who submit genetic data or offer lower wages and salaries to applicants who do not submit it.

Gene therapy

The aim of gene therapy is to change the expression of some genes in an attempt to treat, cure, or ultimately prevent disease (Anderson, 1998). Current gene therapy is primarily experimental, with only a few human clinical trials under way. Gene therapy can be targeted to somatic (body) or germ (egg and sperm) cells.

Somatic level gene therapy

In somatic gene therapy, the genome of certain cells of the individual undergoing therapy is changed, but the change is not passed down to the next generation. The use of gene therapy to cure a disease at the somatic level has no moral drawbacks as long as the ethics of patient safety and other aspects that apply to any new therapy, regardless of its nature, are maintained.

In the early years of gene therapy, the focus laid entirely on treating diseases caused by single-gene defects such as haemophilia, Duchenne's muscular dystrophy, cystic fibrosis, and sickle cell anaemia. The main aim was to find ways to insert the correct gene to substitute for the disease-carrying one. In the late 1980s and early 1990s, the concept of gene therapy expanded to some acquired diseases. More recently, the use of gene therapy is aiming not necessarily to treat a disease but as an alternative way to deliver proteins. It is already possible to use gene transfer technologies to enhance the immune systems of advanced cancer and HIV-infected patients or to promote revascularization of ischaemic tissue in coronary artery disease and peripheral vascular disease.

Gene therapy is still in the preliminary stages, though some successes, especially in blood-cell-related disorders, have been achieved. Very recently, immune response recovery in a type of inherited severe combined immunodeficiency (SCID) has been achieved by gene replacement in bone marrow stem cells using a retroviral vector (Cavazzana-Calvo, 2000).

Ethical aspects of somatic gene therapy

The main ethical problem that research on somatic gene therapy encounters is the fact that it inevitably involves human experimentation. The death of Jesse Gelsinger, the first tragedy ever made public in the history of gene therapy, set alarm bells ringing last year. The 18-year old boy had volunteered at the University of Pennsylvania in US, to help test a treatment for a rare metabolic disorder. He was injected with a disarmed virus carrying a correct copy of the gene that was defective in his own genome. The therapy ultimately caused his death. Controversy was raised after the father of the boy found out about previous experiments carried out on monkeys that had also caused their death and about cases of liver toxicity in other human patients that underwent similar therapies. He had not been properly informed before his son participated in the trial. The need for clear protocols and informed consent (based on

There are fears that widespread genetic testing may lead to discrimination in access to employment, insurance and private health care

Gene therapy is an experimental treatment which attempts to correct mutations in either somatic (body) cells or germ (egg and sperm) cells

knowledge of all the facts) from the patient is obvious. However, these are issues that come up in any research that requires testing on humans at some point, and are not specific to the field of genetics. The adoption of a new medical technique is typically preceded by extensive scientific studies to establish its safety and efficacy. In the case of new gene therapies, these requirements should not be any different. Other disputes may arise over the ethics of conducting investigations that entail experimenting on children and foetuses, and in the case of germ-line therapies, on human embryos.

Germ cell genetic intervention raises special ethical and technical concerns because the modifications will be passed on to future generations

Germ cell level gene therapy

In case of germ cell therapies, the target of genetic intervention is the germ cells, which are the cells containing the genetic information that will be passed on to the next generation. The fact that future descendants will inherit the changes makes the use of gene technology to erase a known genetic defect problematic. Up front, there is not much to question: If it is known that a specific mutation, deletion or insertion in the DNA of an embryo could be changed so that the future baby does not develop a fatal disease or a disorder that will determine his/her well-being (blindness, life in a wheel-chair, etc)... should we not intervene? The answer seems obvious, intervention now is more efficient than repeating somatic gene therapy generation after generation, and even *in utero* somatic gene therapy is too late for some diseases. However, tampering with the germ line is seen by some as playing God and it may be something society is unwilling to tolerate.

Embryonic stem cells, which are cells in pre-specialized state, are of particular interest both for research and for their potential uses in auto-transplantation

Ethical aspects of germ line gene therapy

Though it is still not known how many non-disease human characteristics are, at least in part, inherited, certain traits are substantially influenced by a person's genome. Many of these traits probably result from the interaction of numerous individual genes with environmental factors. Altering the function of one of these genes may have undesired effects on other physical or mental characteristics. Eventually, however, research is likely to reveal techniques for successfully enhancing these non-disease genetic traits. Germ line manipulation creates the possibility of genetic interventions to enhance non-disease traits, for example, to increase strength, stamina, and perhaps even intelligence. Where do we draw the line? What traits are going to be enhanced? Clearly, it would be a great achievement if a child is definitively cured of cystic fibrosis or a particular family line is liberated from the burden of fragile X syndrome or any other inherited disorder. However, to many, eliminating genetic defects is dangerously close to "eugenics", the genetic improvement of the human race.

Apart from the fear of misuse of these techniques for unpalatable eugenic goals, there are also technical uncertainties about their long-term effects. Some people fear that germline gene therapy could go horribly wrong in unexpected ways and that irrevocable mistakes could show up generations later. Some genetic defects have prevailed because at the same time they produced a flaw, they conferred some type of protection against, for example, specific infections. Eliminating specific sequences from the population may therefore have unforeseen consequences.

Stem cells

Stem cells are cells that have the ability to divide for indefinite periods in culture and to give rise to specialized cells. Cells only become mortal after they become specialized into different tissue-types. Human development begins when a sperm fertilizes an egg and creates a single cell that has the potential to form an entire organism. Very soon after fertilization, this cell divides into

identical cells with the potential to develop into any kind of tissue, known as stem cells. As the embryo grows into a foetus and the cells develop, they specialize and lose this potential. Stem cells can also be found in some types of adult tissue. In fact, stem cells are needed to replenish the supply of the cells in our body that normally wear out. However, it is believed that the potential of adult stem cells to grow into any type of tissue is not comparable to that of embryonic stem cells and this is one of the main reasons to pursue research using cells from embryos, not just from adults.

Stem cells will have an increasing role in health care. At the most fundamental level, stem cells could help us to understand the complex events that occur during human development, the genetic signals of tissue/cell specialization. Cancer, many birth defects and other pathological conditions are due to abnormal cell specialization and cell division. A better understanding of these processes will help prevent the errors that cause these pathologies.

Human stem cell research could also dramatically change the developing and testing of new drugs. New pharmaceuticals could be tested using specialized human cell lines, which would shorten the time required for testing.

The most interesting and, at the same time, the most controversial potential application of human stem cells is the generation of cells and tissue that could be used for transplantation instead of donated organs and tissues. This would solve the current need for organs available for transplantation given that demand for organs constantly outstrips supply. Stem cells, stimulated to develop into specialized cells, offer the possibility of a renewable source of replacement cells and tissue to treat a large number of diseases (Parkinson's and Alzheimer's diseases, spinal cord injury, heart failure, stroke, burns, heart disease, diabetes, arthritis, etc). All this is as yet unachievable but research is advancing steadily, firstly, towards understanding the cellular events that lead to cell specialization in humans (to direct these stem cells to become the types of tissue needed for transplantation) and secondly, towards overcoming the problem of immune rejection. Because human stem cells derived from embryos or foetal tissue would be genetically different from the recipient, they would be subject to rejection. Here is where genetics enters into play trying to solve this problem. The use of somatic cell nuclear transfer (SCNT) would overcome the incompatibility issue. In SCNT, the nucleus of a somatic cell from the patient is fused with a donor egg cell from which the nucleus has been removed. With proper stimulation the cell would develop into an embryo which would produce stem cells that could then be stimulated to develop into the tissue needed for transplantation. Because most of the genetic information is contained in the nucleus, these cells would be essentially identical to the patient's so they would not, at least in theory, produce an immune reaction when transplanted. There is a major ethical concern in using this technique since, if carried all the way through to development, it could produce individuals with the same genetic information. This would then be what is generally understood as human cloning (Figure 1).

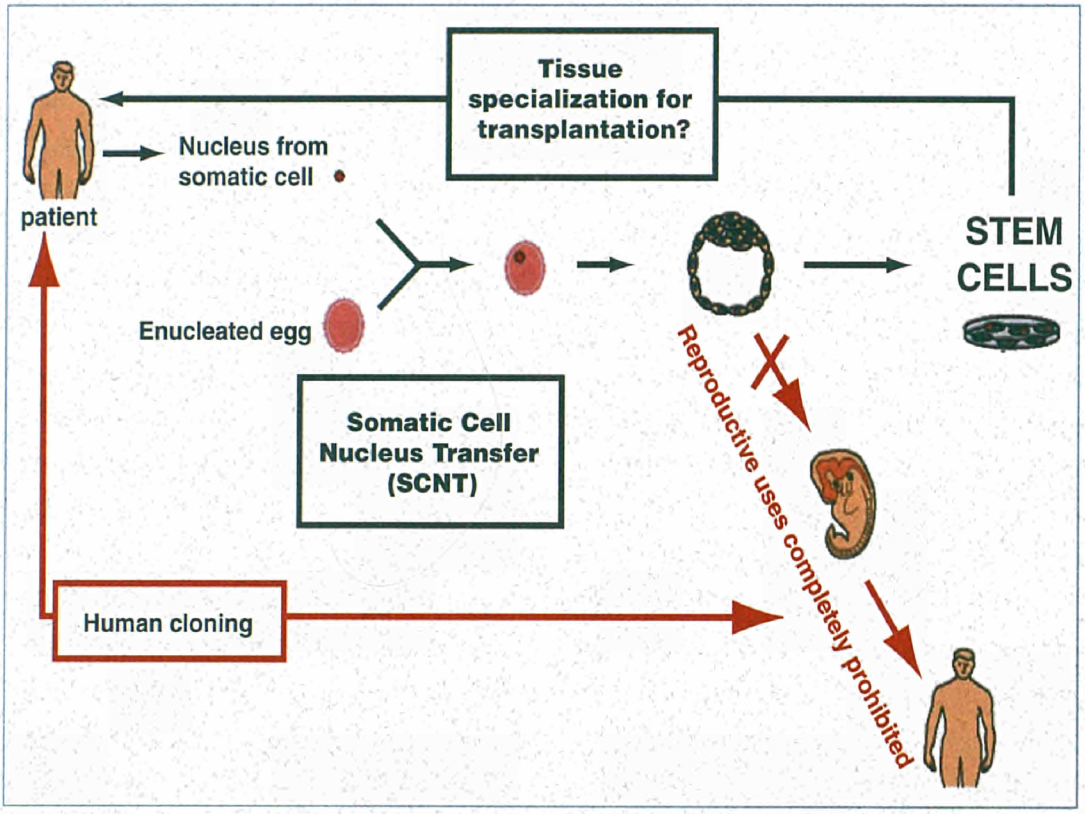
Ethical aspects of stem cell genetic research

Ethics commissions in several countries have already approved research on the human embryo as long as is done before the 14th day of development, while the brain and spinal column of the embryo have not yet become differentiated. Using unused embryos from the residual production from *in vitro* fertilization has been approved in many instances, but the possibility of applying cloning techniques and creating new human embryos as

Human stem cell research could dramatically change the developing and testing of new drugs. New pharmaceuticals could be tested using specialized human cell lines, which would shorten the time required for testing

Stem cells, stimulated to develop into specialized cells, offer the possibility of a renewable source of replacement cells and tissue to treat a large number of diseases

Figure 1. Potential use of stem cells for auto-transplantation



The British Government's decision to approve human embryo cloning for therapeutic purposes sparked off a debate in the European Union, leading to a communication stating the EP's disapproval of the move

part of research has sparked off a great deal of controversy. While cloning techniques not related to human reproduction might provide effective medical tools, there are objections to them on the grounds that generating human embryos for research could pave the way for reproductive cloning.

In August 2000, the US National Institutes of Health (NIH) released guidelines for NIH funded research using human stem cells derived from human embryos or foetal tissue. For studies using cells derived from human embryos, NIH funds may be used only if the cells were derived from frozen embryos that were created for the purposes of fertility treatment and were surplus to clinical needs. Also in August 2000, the British Government decided to ask the Parliament to approve human embryo cloning for therapeutic purposes, this is one step further towards the use of human embryos for research, although cloning for reproductive purposes will remain prohibited. This proposal was based on a report by the British Ministry for Health which recommended allowing research involving human embryos for the purpose of developing tissues from embryonic stem cells to treat diseases and the use of SCNT for producing stem cells for cell and tissue therapy. This generated debate in the European Union (EU). The European Parliament (EP) responded to this controversy with the adoption of a communication mentioning that therapeutic cloning, which involves the creation of human embryos for research purposes, poses a profound ethical dilemma, it implies reaching a point of no return in the field of research and is contrary to the policy adopted by the EU. The EP invited the British government to review its position on the cloning of human embryos and the members of the British Parliament to reject the controversial proposal.

The European Commission (EC) cannot take any legal action because Member States under the EU Treaty retain full prerogative to legislate on ethical matters. In fact, legislation differs widely

between Member States, reflecting a diversity of positions on the issue. However, Community action on biotechnological research is based increasingly on the most rigorous ethical principles. The Fifth Framework Programme (FP5) on Research and Technological Development (1998-2002) excludes projects involving the cloning of human embryos for reproductive Innovation Technology purposes from funding. No research projects on therapeutic cloning are currently being funded, although financial support is being given to bioethical research projects on the potential risks and benefits of cloning technology. The FP5 also finances complementary approaches aimed at developing new cell therapy techniques, particularly on the basis of cell differentiation. Community research is scrutinized by the European Group on Ethics in Science and New Technologies[1] (EGE) that was set up in January 1998 to help the EU internal market to operate in accordance with Europe's ethical values.

A common European debate on the ethical evaluation of research

The rapid development of science is creating a major challenge for society. The ethical evaluation of the possible impacts of the research in the field of genetics may be too great a burden for policy-makers, even if they rely on scientific, technical and ethical advisors in the decision-making process. Society at large may also need to play a bigger role than it has been accustomed to. The dialogue between science and society needs to be more fluent, as shown in the latest Eurobarometer study "The Europeans and biotechnology" (Eurobarometer 52.1). In this study only 11% of the population in the EU (13% men and 9% women) feel they are adequately informed about biotechnology though up to 41% of them would be willing to participate in public debates or hearings concerning biotechnology. Society needs to be better informed for the obvious reasons of public trust and transparency but additionally because it needs to involve itself in the ethical evaluation of scientific research. Especially in areas like human genetics where the implications are so significant, decisions should be taken with the participation of all stakeholders. The research community needs to acknowledge to society the moral and social consequences of their work. Science is no longer considered morally neutral and the control of technological advances is not exclusively left to the "experts", as it was in the past. These evaluations go beyond the technical aspects of research and enter grounds of purely ethical responsibility. Society wants to participate actively in regulating those procedures and techniques which have a powerful impact on the present and future of humanity. Just delegating the task of defining research and development policies to public and private research institutions is perceived as being inadequate. Channels of citizen participation need to be improved and the public needs to be better informed on scientific matters.

In the case of the EU, one major step towards achieving this objective of societal involvement has been built into the design of the future European Research Area[2] (ERA). In its communication of January 2000 about the ERA, the European Commission states its aim to develop a shared vision of ethical issues of science and technology and to foster a coherent approach to these issues. In the "First Step towards a European Research Area" document (2000-48.EN), the Commission lays down the initial action plan for the implementation of the ERA, concentrating first on the priorities set by the European Council. Among these priorities, the Commission is planning several communications, one of them, set for the beginning of 2001, on the social and ethical aspects of research in Europe. One of the Commission's approaches to handling these ethical problems arising from science and technology is to promote a clear statement of the values shared by Europeans.

Science is no longer considered morally neutral and the control of technological advances is not exclusively left to the "experts", as it was in the past. These evaluations go beyond the technical aspects of research and enter grounds of purely ethical responsibility

Recent surveys suggest the European public is concerned about biotechnology and would like greater involvement in debates, but feels itself to be ill-informed and lacking the knowledge necessary to understand the issues

Keywords

gene therapy, genetic testing and diagnosis, gene manipulation

Notes

1. Towards a European Research Area, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, January 2000.
2. For more information on EGE see:
http://europa.eu.int/comm/secretariat_general/sgc/ethics/en/index.htm

References

- Anderson, W., *Human gene therapy*. Nature **392** (suppl 6679): 1998, pp. 25-30.
- Cavazzana-Calvo, M., Hacein-Bey, S. de Saint Basile, G., Gross, F., Yvon, E., Nusbaum, P., Selz, F., Hue, C., Certain, S., Casanova, J-L., Bousso, P., Le Deist, F., and Fischer. A., *Gene therapy of human severe combined immunodeficiency (SCID)-X1 disease*. Science 288: 2000, pp 669-672.
- Dequeker, E., and Cassiman, J.J., *Evaluation of CFTR gene mutation testing methods in 136 diagnostic laboratories: report of a large European external quality assessment*. Eur J Hum Genet. 6(2): 1998, pp 165 - 175.
- UK Department of Health. *Stem Cell Research: Medical Progress with Responsibility: a report from the chief medical officer's expert group reviewing the potential of developments in stem cell research and cell nuclear replacement to benefit human health*, 2000.
- US Department of Health and Human Services, Public Health Service, National Institutes of Health. *NIH Guidelines for Research Using Human Pluripotent Stem Cells* 2000.

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BRIEF NOTE

Ethical assessment of Life science research projects

Laurence Cordier, *European Commission*

Introduction

The European Commission has supported research in the area of the Life Sciences, medicine and biotechnology for many years now. It is the responsibility of a funding institution to promote the highest ethical standards and to make sure that it supports research that is performed in a responsible manner.

This principle is embodied in the article 7 of the Fifth framework programme for research, technological development and demonstration activities[1] which reads:

"All research conducted pursuant to the Fifth Framework programme shall be carried out in compliance with fundamental ethical principles including animal welfare requirements, in conformity with Community law."

In its opinion no. 10 on the Fifth framework programme, the European Group on Ethics (EGE)[2] has given the Commission some guidance on how one should deal with ethical aspects of the 5th Framework programme. Accordingly, for the implementation of the programme "Quality of Life and management of Living resources"[3] in particular, a systematic ethical assessment of issues arising from projects has been organized. This article further describes how the Commission services organized the ethical assessment of projects submitted for funding in the area of the Life sciences.

Proposal submission

The "Quality of Life" programme imposes specific requirements on all proposers concerning ethical issues. Proposers have to describe the ethical issues arising from the research they intend to conduct in their proposals. They should specify whether the project involves research involving human beings, use of human embryos, use of human tissues, use of personal data or genetic information, and whether the research involves the use of non-human primates or other animals. Proposers also have to describe the measures taken to address the ethical issues that emerge.

Scientific evaluation

In the first instance all proposals for research which are submitted undergo a thorough scientific evaluation during which a first assessment of the ethical issues is made. For example the evaluators indicate if they believe that in some projects ethical issues are not addressed by the proposers in a satisfactory manner.

Ethical review and the report

An ethical review is performed only for projects that have already been selected for funding and which raise serious and/or controversial issues, such as research using foetal and embryonic tissues, or research involving non-human primates. In addition, special attention is also paid to projects

involving persons unable to give a valid consent (including children) or clinical trials performed outside the Member states, and research using personal data and genetic data.

The main difficulty in assessing ethical issues at a European level instead of at a more local level is the question of the reference documents. What rules and ethical principles should serve as a reference?

In addition to international guidelines such as the Declaration of Helsinki, the Convention on Human Rights and Biomedicine[4], the ethical review is following the guidance of the different opinions of the European Group on Ethics, for example the opinion on "research involving the use of human embryo in the context of the 5th Framework programme" and the opinion on "human tissue banking".

The ethical review panel

The review is performed by a panel of independent experts from various disciplines representing different societal interests (such as animal protection groups, patient organizations, industry, etc.) Of course experts should also be coming from different Member states to represent the different cultures present in Europe.

A variety of issues are covered by the review, ranging for example, from vaccine trials to use of human embryonic tissues. The same panel may review the use of animals and, in particular, projects involving non-human primates and clinical trials on human beings. Therefore the range of competencies within the panel must be very wide.

Negotiation

The reports of the ethical review panel will be transmitted to the coordinators of the projects at the time of the contract negotiations. The panel's recommendations have to be taken into account by participants before the contract is signed. The technical annex must be amended accordingly. Finally, copies of panel opinions/approvals have to be forwarded to the Commission.

Conclusion

The ethical assessment of life science research proposals that is organized by the Commission services is not in any way replacing the ethical review of research that is performed at national or local level. Participants in research projects must in any case conform to their national regulations and their codes of practices, which may require an ethical review and/or a prior authorization.

Through the ethical assessment of research proposals submitted for funding the intention is to show the whole European research community that ethical issues have to be dealt with according to the highest standard of protection for human beings and animals. The overall aim is that it remain clear that EC funded research in Life science is conducted in a responsible way.

About the author

Laurence Cordier studied Community and international law at DESS, Paris (F) and obtained a Master in Comparative Law from Washington DC (USA). Since 1993 she has been at the European Commission's DG Research, where she works on ethical and legal aspects of the life sciences.

Notes

1. Decision 182/1999/EC, JOCE 1.2.1999 L26/1.
2. For more information see: **http://europa.eu.int/comm/secretariat_general/sgc/ethics/en/**
3. Council decision 1999/167/EC, JOCE 12.3.1999 L64/1.
4. Convention on the protection of human rights and dignity of human being with regard to the application of biology and medicine, signed in Oviedo on 4.04.1997, ETS No. 164.

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BRIEF NOTE

Teaching Science, Teaching the Responsible Conduct of Research

Rachelle D. Hollander, *NSF*

Introduction

The time is long past since teaching staff and others with responsibility for educating, training and supervising researchers should be including formal training in the responsible conduct of research in those efforts. In 1997, the regions of Asia, Western Europe, and the Americas (where statistics are available) granted 159,235 doctoral degrees in all fields of science and engineering. Standing at the peak of a large educational enterprise that represents a major social investment, the numbers indicate the changed context in which post-graduate education operates.

Given the scale of these investments, and the importance to society of results from research activities that involve post-graduate and post-doctoral assistance, it is not surprising that questions arise concerning the roles and responsibilities of post-graduates, post-doctoral associates, teaching staff, and their institutions. Tighter coupling between academic and other social institutions has prompted increased attention to ethical aspects of the relationships between established and trainee researchers. The system is showing the strains of increasing numbers as well as increasing calls for accountability from post-graduate students themselves and the governmental funders and sponsors of post-graduate education. Adequate response to these stresses requires the attention of academic institutions and professional associations. Most important, perhaps, are the responses at the level of departments and programmes actually producing new PhDs.

A particular impetus for change in this arena has been increased social and governmental attention to questions of research misconduct. These concerns resulted in new regulations in the US that require institutions to have procedures in place that respond to allegations; many other nations have implemented procedures to respond to this concern. Governmental and academic institutions as well as scientific and professional associations regard this as a broader mandate for education in research integrity. In the US, the National Institutes of Health has established requirements for ethics training for all research staff that have implications for training, mentoring, and supervision.

Professional associations have been custodians of good practice for their members as well as for practitioners and researchers who may not be members but draw on the body of knowledge and relevant expertise that these associations incorporate. Today's world requires that experts work with others with very different specialities more often than in the past; the need for these group or team efforts raises additional issues for good training, mentoring, and supervision, as well as for the effective review of research results.

For persons in academic research environments to do the right thing, they require and deserve assurance that others will do their share, and that they will be protected if difficulties arise. To foster this ethic, post-graduate departments or groups should develop adequate written statements of the terms of post-graduate study, including policies about conflict of interest and training in the responsible conduct of research, and assign necessary duties to individual teaching staff members. Such statements should be distributed to trainees. Individual members of teaching staff often have responsibilities in admitting students; similarly, they can assume responsibilities in advising students, post-doctoral associates, and new staff, and in placing graduate students in postdoctoral positions and jobs. Tasks that can help post-graduate students and post-doctoral associates succeed – such activities as writing proposals or research reports – can also be parcelled out among staff, as can assignments for making students aware of ethical aspects of research and professional activities.

To do a good job, mentors and trainees need to be educated in the research standards of their fields. An approach to this subject area would be expected to incorporate attention to foundational principles and concepts with which issues particular to the field or fields of study can be examined. The curriculum would examine issues of ethical conduct in scientific research, and professional behaviour, recognizing the influence of organizational and social contexts on problem definition and response capabilities. Cases would provide illustrations of problems and better and worse approaches to their resolution. They should give students opportunities to develop their analytical skills and emotional understanding of the situations in which they have to operate. They can also provide insight into social perceptions of the influence of research and technology on social welfare and justice.

As parts of the core of such curricula, students need to be familiar with the relevant codes of ethics. In experimental work, standards of laboratory practice or laboratory safety need to be discussed; and the same is true for standards of fieldwork and survey practice. Regulatory requirements concerning animal and human subjects need to be well understood. Besides the important area of potential harms, standards for ethical practice of human subjects research include matters of privacy and confidentiality, consent, and community protection. In research in the social and behavioural sciences, complex questions concerning deception or stigmatization of individuals or communities may need particular care, particularly in the context of research on vulnerable populations, in other cultures, or involving deception. All teaching staff and trainee researchers should be familiar with definitions of research misconduct and the policies of their programme and institution. Responsible use of statistical methods, where appropriate, needs to be understood, as do requirements for stewardship of records and data and ownership of ideas and intellectual property. Standards for responsible authorship and peer review also need to be understood, and the discrepancies that may exist between different fields need to be examined. These are areas where departments and institutions as well as professional associations and scientific societies can have much to offer.

A broader and deeper approach to research ethics might examine the normative consequences of social commitment to innovation. This approach would encourage students and staff to examine processes and outcomes for setting research priorities as well as ethical dimensions inherent in and consequent to research outcomes and technological applications.

In conclusion, programmes and departments should create systems that specify the duties of staff

involved in research ethics training, and describe how their performance should be evaluated. Recent publications and guidance from national bodies and professional associations, as well as books and articles by individual scholars, can be helpful in developing materials and activities on research ethics that are responsive to the needs of new post-graduate students and members of the teaching and research staff. Training for teaching staff and advisors, as well as curriculum development activities, will be needed. One of the side benefits of increased attention to structural reforms and ethical research practice in post-graduate education might be expansion of researchers' capabilities to exercise responsible social leadership.

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ABOUT THE JRC

The Joint Research Centre (JRC), one of the Directorates General of the European Commission, carries out research and provides technical know-how in support of European Union (EU) policies. Its status as a Commission service, which guarantees independence from private or national interest, is crucial for pursuing this role.

The JRC implements its mission through specific research programmes decided by the Council upon advice from the European Parliament falling under the European Union Framework Programmes for research and technological development. The work is funded by the Budget of the European Union with additional funding from associated countries. The work of the JRC includes customer-driven scientific and technical services for specific Community policies, such as those on the environment, agriculture or nuclear safety. It is involved in competitive activities in order to validate its expertise and increase its know-how in core competencies. Its guiding line is that of "adding value" where appropriate, rather than competing directly with establishments in the Member States.

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- The Environment Institute (EI)
- The Space Applications Institute (EI)
- The Institute for Health and Consumer Protection (IHCP)
- The Institute for Prospective Technological Studies (IPTS)

Further information can be found on the JRC web site:
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ABOUT THE IPTS

The Institute for Prospective Technological Studies (IPTS) is one of the eight institutes making up the Joint Research Centre (JRC) of the European Commission. It was established in Seville, Spain, in September 1994.

The mission of the Institute is to provide techno-economic analysis support to European decision-makers, by monitoring and analysing Science & Technology related developments, their cross-sectoral impact, their inter-relationship in the socio-economic context and future policy implications and to present this information in a timely and integrated way.

The IPTS is a unique public advisory body, independent from special national or commercial interests, closely associated with the EU policy-making process. In fact, most of the work undertaken by the IPTS is in response to direct requests from (or takes the form of long-term policy support on behalf of) the European Commission Directorate Generals, or European Parliament Committees. The IPTS also does work for Member States' governmental, academic or industrial organizations, though this represents a minor share of its total activities.

Although particular emphasis is placed on key Science and Technology fields, especially those that have a driving role and even the potential to reshape our society, important efforts are devoted to improving the understanding of the complex interactions between technology, economy and society. Indeed, the impact of technology on society and, conversely, the way technological development is driven by societal changes, are highly relevant themes within the European decision-making context.

The inter-disciplinary prospective approach adopted by the Institute is intended to provide European decision-makers with a deeper understanding of the emerging S/T issues, and it complements the activities undertaken by other Joint Research Centres institutes.

The IPTS collects information about technological developments and their application in Europe and the world, analyses this information and transmits it in an accessible form to European decision-makers. This is implemented in three sectors of activity:

- Technologies for Sustainable Development
- Life Sciences / Information and Communication Technologies
- Technology, Employment, Competitiveness and Society

In order to implement its mission, the Institute develops appropriate contacts, awareness and skills for anticipating and following the agenda of the policy decision-makers. In addition to its own resources, the IPTS makes use of external Advisory Groups and operates a Network of European Institutes working in similar areas. These networking activities enable the IPTS to draw on a large pool of available expertise, while allowing a continuous process of external peer-review of the in-house activities.

The IPTS Report is published in the first week of every month, except for the months of January and August. It is edited in English and is currently available at a price of 50 EURO per year in four languages: English, French, German and Spanish.

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