

This response was submitted to the consultation held by the Nuffield Council on Bioethics on Emerging biotechnologies between April 2011 and June 2011. The views expressed are solely those of the respondent(s) and not those of the Council.

Ethical issues in emerging biotechnologies

Response to consultation of Nuffield Council on Bioethics on emerging biotechnologies.

A.G. SPAGNOLO, VIVIANA DALOISO, FRANCESCA GIGLIO

Institute of Bioethics, School of Medicine “A. Gemelli”, Università Cattolica del Sacro Cuore
– Roma (Italy)

Preliminary remarks

Regarding the consultation on the Ethical issues in emerging biotechnologies we divided our contribution into two parts. In the first one we try to outline the context where the main issues, with regard to emerging technologies, arise. The second is focused on a particular technology, nanotechnology, the field where our Institute of Bioethics. has developed a specific experience.

We based our position on the cognitivist aristotelic-thomistic ethical approach: this perspective is founded on the human person as a reference-value in the reality, around which all the ethical judgements should be subordinated.

Part I

1) Defining “emerging biotechnologies”: context , features and the main ethical issues

According to M. Moran - and as noted by Nuffield Council - it is not easy to collect emerging biotechnologies under a single and clear definition: Moran points out that a first distinction may be done diversifying the single technique intended for a specific use such as in

vitro fertilization (IVF), from wider projects that require the use of a variety of technologies as in the case of human enhancement.

In our opinion, in order to define the complex debate on “emerging technologies”, one should also take into account the convergence of three factors:

1. the scientific and technological developments and the emergence of new techniques (such as nanotechnology, synthetic biology, just to cite some of them);
2. the applications of “novel” and “old” technologies in a sort of “new way” (such nanotechnologies and genetic engineering for human enhancement)
3. the use of more or less innovative technologies for a “larger projects” (for example, the human enhancement)

This complexity may be outlined using the concept of the “technological convergence” that seems to well summarize the context or the characteristics of emerging technologies.

The theory of converging technologies¹ is based on the assumption that at the present we are facing with a "comprehensive understanding of the structure and behavior of matter from the nano-scale up to the Most Complex Discovered system yet, the human brain" capable of leading to, through the unification of science and a holistic investigation, “technological convergence and a more efficient societal structure for reaching human goals". We believe that the premises of this theory are common to many fields of current research in emerging biotechnologies: a) the whole of reality is intelligible according to the rules already showed in nano-scale: from this scale science technology can understand, control and reproduce every inorganic and organic structure, b) the Nano-bio-cogno-info (NBCI) technologies open to a radical transformation of the means as analytical methods, new tools and new materials, c) the unified scientific approach allows us to understand the world as a complex and hierarchical system; d) NBCI technologies make it possible to increase human performance, including mental, physical and social skills².

The comprehensive project of the technological convergence is structured as follows: a) societal productivity, in terms of well-being as well as economic growth; b) security from natural and human-generated disasters; c) individual and group performance and

¹ ROCO M.C., BAINBRIDGE W.S., NATIONAL SCIENCE FOUNDATION, *Converging Technologies for Improving Human Performance. Nanotechnology, Biotechnology, Information Technology and Cognitive Science*. NSF/DOC-sponsored report, June 2002, Arlington (Virginia).

² *Ibidem*

communication; d) life-long learning, graceful aging, and a healthy life; e) coherent technological developments and their integration with human activities; f) human evolution, including individual and cultural evolution³.

However, this approach, that is both of scientific and cultural-anthropological nature, involves a number of issues shared with the context of emerging biotechnologies, namely:

- issues about risks, more or less predictable, both on the individual and the environment;

- issues about the anthropological perspective. In fact, functionalism is used as the main ethical and anthropological approach, funded on the scientific reductionism; the epistemological model has a mere “techno-scientific” nature: “technoscience” is imposing itself as unique and self-referring reflection that becomes the only criterion for human action. It is necessary, however, to take into account the human person’s good and morality and acting accordingly that goes beyond the norms that shapes the scientific epistemological model. Science, as human action, must refer to something outside herself;

- issues about definition of “health” and the epistemological question about the proper aims of medicine” (*restitutio ad integrum* or “well being” or “enhancement”).

2) *Evaluating ethical issues in emerging biotechnologies*

In the debate concerning emerging biotechnologies, social and ethical issues are often analyzed in the light of a procedural ethics. Many discussions, for instance, are related to autonomy and justice: in these issues it is noted that progress can lead to widening the social gap in accessing new discoveries: it raises the alternative between a free market and, instead, a regulated governance for an equitable resources distribution and a fair access to the new treatments. We believe that, this alternative emerges from the question concerning "substantial" freedom: it should be questioned if in a highly competitive society the subject is really free “not to choose”, for example, treatments that could increase his/her ability or opportunity. Questions about self-determination concern the issue of risk as well; the case of possible risks arising from the use of treatments not only for therapeutic purposes – e.g. enhancement - raises questions of individual’s autonomy: has the subject the right to exercise

³ *Ibidem*

self-determination as expression of his/her preferences even when faced with a high risky treatment?

Issue about “risk” is, also, quite common: in discussing on this topic, at first glance it seems obvious to refer only to the physical harm. However, hypothetical harms should be taken in account in other areas related to the application of new technologies: some examples are the widening the social gap in access to new treatments - that, in the case of enhancement, could lead even to a separation between “enhanced” and “not-enhanced” classes -, or transformation of the experience - again related to enhancement.

Some technologies or application as human enhancement technologies, synthetic biology, IVF etc. arise issues about “dignity”, “*playing good*”, “human nature”. In our opinion, in every bioethical discussion about treatments applied on human health it is necessary to consider that techno-science is an expression of human action and, moreover, emerging biotechnologies are applied on human being: every choice or project in this field are not neutral or merely “scientific” but ethically meaningful.

The outlined issues have to be treated taking in account the real good and interest of the person, perspective based on recognition of the person considered in its complexity of corporeality and spirituality as a core value. The most immediate consequences are a) the prohibition to act against a human being mortifying his personal lifestyle, taking in little account its essential autonomy and freedom, i.e. the refusal of all forms of oppression against the person; b) the prohibition of using any human being for other purposes than their own good, i.e. the negation of all forms of exploitation of the person; c) the prohibition of treating any human being as a thing without value, or as an irrelevant specimen of the human race, or as an object that must acquire the right to be recognized as a person, i.e. the negation of all forms of discrimination against the person.⁴ This approach intends to highlight a *triangular* connection among bio-medicine, anthropology and ethics. In particular, it affirms the importance to conduct ethical analyses referring to an anthropological view the lack of which would make the process of analysis incomplete. Other methods in bioethics like casuistry or principlism do not take the anthropological factor into account in this manner.⁵

⁴CARRASCO DE PAULA I. *Il concetto di persona e la sua rilevanza assiologia: i principi della bioetica personalista*. *Medicina e Morale* 2004; 2: 265-278.

⁵SACCHINI D. VIRDIS A. REFOLO P. PENNACCHINI M. CARRASCO DE PAULA I. *Health Technologies Assessment (HTA): ethical aspects*. *Med Health Care and Philos* (2009) 12:453–457

Ethical evaluation of each technology should be assessed through the following method in three steps (“Triangular Model”): 1) data collection (gnoseological level); 2) ethical/anthropological analysis (justifying level); 3) ethical evaluation (normative level).⁶

First step (the point “A” of an ideal triangle) is an in depth study of all factual data concerning the technology in question. In order to achieve it, putting these questions could be fruitful: a. what is it about?; b. how is it to be done?; c. why is it to be done?; d. what consequences?

Second step (point “B”) is the ethical and anthropological understanding of facts or, in other words, the analysis of eventual values at stake or in conflict. In order to realize it, the following operating criteria/principles are utilized: a. the defense of human physical life; b. the contextual exercise of freedom and responsibility within the decision-making process; c. the safeguard of the therapeutic principle, according to which the human person has to be treated as a whole of body and soul; d. the principles of sociality and subsidiarity, for which public and private authorities are called to help all persons in need.

The third step (point “C”) consists of the ethical evaluation that should guide the practical choices.

The main advantage of this approach is to provide a complex axiological and anthropological model which matches a multi-disciplinary approach to the ethical issues of synthetic biology as applied to human health. It will consider both the scientific-technical aspects of synthetic biology, as well as the complexity of human experience and human condition and the dimension of human health within it.

Part II

Nanotechnologies as emerging technologies: outlining “old” and “new” ethical issues

⁶ Same model was recently used in ethical analysis in emerging fields of nanotechnology (particularly nano-medicine) and HTA: see SPAGNOLO AG, DALOISO V. *Outlining ethical issues in nanotechnologies* Bioethics (2009) 23, 7: 394–402; SACCHINI D, VIRDIS A, REFOLO P, PENNACCHINI M, CARRASCO DE PAULA I. *Health Technologies Assessment (HTA): ethical aspects*. Med Health Care and Philos (2009) 12:453–457.

Technologies, as an expression of human action, arise many implications: some of them are common to all technologies, other are specific to some of them because of the specific characteristics that technology: this is the case of nanotechnologies. While some Issues are common to all technologies, and that's why some Authors refer to them as "old issues", other are specific to nanotechnologies because of their specific characteristics, calling for a "nanoethics". In the first case, the ethical aspects are evaluated in the perspective of "main" issues (autonomy, risks and benefits, distributive justice ..). In the second, they refer to the novelty given by these technologies: nanoparticles toxicity, biocompatibility, human enhancement, clinical trials.

The problem lies specifically in interpreting the concept "nanoethics": those who do not share the need of a specific bioethics for nanotechnologies base their considerations on the fact that these technologies do not produce a change of values and do not require the introduction of new ethical principles. At a closer look, nanoethics does not clamor for the introduction of new principles or values but for the assessment of nanotechnologies in the domain of a specific reflection and not in that of general concerns. In this light, it is unquestionable that the possibilities of combining science and technologies to create more tailored and effective therapies represent a benefit for the patient, nevertheless, these benefits must be interpreted in the light of the risk associated with the treatment. When it comes to nanotechnologies, this situation turns to be thorny because of the incertitude associated to nanoparticles, deriving from size effects.

Issues related to the novel properties that have consequences both on the assessment of safety and efficacy, nanotechnologies raise, among others, the following ethical questions:

- Nanotechnologies make difficult the identification of a systematic toxicological risk assessment of nanomaterials and products. This lack raises further issues when it is to obtain the consensus within clinical trials, which are in itself complex because of the lack of *in vivo* study in animals.

- It is difficult to define, at least in the short period, all the implications (for example, harms) deriving from these novel technologies.

- Nanotechnologies, due to their novelty, may produce a gap between scientific research and foreseen outcomes.

- Many nanotechnologies are home-care technology: this could cause the “depersonalization” of many physician-patient relationships, causing changes in the way the medical profession is practised.

- Managing information and privacy is an ongoing problem: there is the worry that nanobiotechnologies, able to reduce dimensions and increase functions, may be used for other than medical purposes, for example, to monitor human life and personal privacy. Moreover, it could be difficult to store the large amount of data coming from these devices.

- Another ethical issue deals with the consideration for which diagnostic nanotechnologies may produce incidental findings of pathologies, that still have not explained their symptoms. Such findings may put patients and clinicians in the need of clarifying their clinical relevancy. In other words, diagnostic investigation of incidental findings may require further investigations. This is thorny since incidental findings do not relate to the original reason of the use of nanotechnologies but often force patients into an additional diagnostic investigations with all its consequences.

- Nanotechnologies may be used to enhance, repair or replace human characteristics.

With regard to the “risk” associated with nanoparticles, it should be considered that, due to properties, this risk may be different. For these reasons, some Authors⁷ have proposed to apply to nanotechnologies the Precautionary Principle, considering both its “strict” form, according to which it is requested the inaction when action might pose a risk and the “active” form, choosing less risky alternatives when they are available, and for taking responsibility for potential risks. The application of the Precautionary Principle in a restrictive way can lead to the suspension of any experiment and research in this field, although some benefits are shown; on the other hand, the use of the “active” principle, may facilitate the use of objects or products that show a non excessive risk but that it is not yet defined.

To a closer look, the inaction poses at least three severe risks⁸: 1. no other solution may be found for certain pressing problems. 2. inaction on the part of responsible people could simply lead to the development and use of molecular manufacturing by less responsible people. 3. lack of understanding of the technology will leave the world ill-equipped to deal with irresponsible use.

⁷ C. PHOENIX, M. TRADER, *Applying the Precautionary Principle to Nanotechnology*, Center for Responsible nanotechnology (CRN), 2003. <http://crnano.org/precautionary.htm> [accessed 20 Julyo 2009].

⁸ *Ibidem*.

According to these Authors, it is opportune to use the principle in the “active” form, keeping the risk on acceptable level: “promoting the responsible development of MNT (*molecular nanotechnology*) not because it is *safe*, but because we believe it is *risky*”.

In the light of what has been said, the suggestion may be the “proportionality”: the research on nanotechnologies is ongoing; this situation offer the possibility to evaluate the implications while doing the research.