

The human centred approach to bionanotechnology in telemedicine: ethical considerations

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Abstract

The information and communication technologies (ICTs) field is expanding rapidly and affecting several domains of mankind, as for example healthcare. Therefore, ICTs can act as an enabler or a provider these fields through telemedicine. Consequently, promoting an human centred and ethical approach is the primary challenge concerning ICT healthcare innovation. Simultaneously, can we deter- or at least discourage- innovation that serves malicious ends, or that causes serious threats to humanity?

So, the purpose of this contribution is to discuss the relationship between ICT evolution and healthcare, particularly concerning a specific correlated research fields: bionanotechnology and telemedicine. For that, we will focus in its applications, and sort of ethical and moral dilemmas encompasses.

Introduction

Innovation by tradition was viewed as a linear process: from basic research to technology progress, test/evaluation, demonstration, deployment, commercialization, and ultimately, market penetration. And possibly, if successful, market saturation, obsolescence, and finally substitution. Human (and social) factors- needs, desires, demands, behaviour- were considered either not intuitively, anecdotally, coincidentally, mechanically, and often reactively. Innovation was firstly defined as hard science, engineering, and production, with marketing and sales trailing behind, as “army camp followers”. Therefore, the primary challenge to promulgate a more human centred and ethical approach to manage and account for innovation is:

- can we encourage innovation that adds net social value? That is, whose benefits clearly outweigh its costs?
- at the same time, can we deter- or at least not encourage- innovation that serves malicious ends or that causes serious threats to humanity?

Plus, it seems obvious that healthcare innovation have huge benefits from ICT; however, such technologies have the ability to affect positively and negatively patients, and so society must investigate their impacts, namely in telemedicine. Nevertheless, the main purpose is to approach bionanotechnology as a research field. But, how can we define bionanotechnology? As we will demonstrate, such concept is still an ongoing debate, and for that we need to address two levels of arguing:

- what is biotechnology? Which are its applications, particularly medical applications? What ethical and moral dilemmas arise?
- what is nanotechnology? Which are its applications, particularly medical? What ethical and moral dilemmas occur?

Biotechnology can be broadly defined as the condition of using organisms or their products for commercial purposes. It has been used into food, crops or domestic animals; but, recent developments in molecular biology have given biotechnology a new meaning, prominence, and potential. It is (modern) biotechnology that has captured the attention of the public, and of course encompasses a great deal of ethical and moral dilemmas.

Nanotechnology is the creation of functional materials, devices, and systems through control of matter on the nanometer length scale, the exploitation of novel properties and phenomena developed at that scale (Bonsor, 2002). Throughout literature it is possible to find several examples of nanotechnology applications: giant magnetoresistance in nanocrystalline materials, nanolayers with selective optical barriers, nanomedicine robots, etc. (Institute of Molecular Manufacturing, 2003). Concerning the possible and moral dilemmas of such technology it is usual that philosophers, ethicists and many scientists frequently speak as if such objects will exist in a nearly future, but in fact they already exist which clearly creates a policy vacuum (Moor, 2001).

Only after such discussion is feasible to acknowledge the aim of your contribution: how can we define bionanotechnology as a research field? Which are its medical applications? What sort of ethical and moral dilemmas are involved? And, could the level of such dilemmas be a sum of biotechnology and nanotechnology, or imposes new challenges?

Background

E-health versus telemedicine

ICT have been developing rapidly for several decades now. Thus, the health sector has witnessed the creation of a vast number of applications:

- telemedicine, which is leading to a radical change in medical practices and in practitioner/patient relationship;
- e-health, which provides sources of information and new services for practitioners and patients;
- smart cards, which allow claim forms to be sent electronically and may, in the middle term, be used for other services and procedures.

Accordingly, previously to our stream analysis we need to debate some important features: understanding why such health technologies are so innovative? And, what characterizes telemedicine and e-health? New health technologies not only disorder relationships we have with other people, they in addition redefine our connection towards our own body and our sense of being healthy or sick, our sense of control over our body and its parts. As Webster (2007) argues, such technologies possess the ability to reinvent the boundaries of our body in

space and time by tumbling them to their basic level of biological assembly, embracing therefore a great deal of ethical dilemmas.

The terms telemedicine and e-health are sometimes confused or broadly used interchangeably, however what is the correct word? How the mass in terminology has emerged? Initially the word “telemedicine” was commonly used, however today we have moved forward...

The term telemedicine is a combination of two words (the Greek *τήλε* equal to tele, which means “at a distance”; and, *ars medicina* meaning “healing”). Telemedicine can be defined as a delivery of healthcare and exchange of health care information across distance (Wootton, Craig & Patterson, 1999). Or, the World Health Organization defines it as “the delivery of healthcare services, where distance is a critical factor, by all healthcare professionals using information and communications technologies for the exchange of valid information for diagnosis, treatment and prevention of diseases and injuries, research and evaluation, and for the continuing education of healthcare providers, all in the interests of advancing the health of individuals and their communities” (World Health Organization, 2005, pp. 1). Given such definitions we may claim that telemedicine can be divided into three areas: aids to decision-making, remote sensing, and collaborative arrangements for the real-time management of patients at a distance. However, some have suggested that telemedicine is not a technology *per se* but rather a *technique* that delivers care remotely (Loane & Wootton, 2002). Even so, the need for moral endeavour must be a reality.

Contrarily, the term e-health is considered a neologism. So, e-health is “today’s tool for substantial productivity gains, while providing tomorrow’s instrument for restructured, citizen-centred healthcare systems and, at the same time, respecting the diversity of Europe’s multi-cultural, multi-lingual healthcare traditions. There are many examples of successful e-health developments including health information networks, electronic health records, telemedicine services, wearable and portable monitoring systems, and health portals” (Commission of the European Communities, 2004, pp. 4). Gustafson & Wyatt (2004) define it as patients and the community using the internet or other electronic media to propagate or supply access to health and lifestyle information or services. This differs from telemedicine, in which there is a health professional at one or both ends of the communication.

So, Eysenbach (2001) into the 20th editorial concerning Journal of Medical Internet Research acknowledges the following major characteristics for e-health:

- efficiency- one of the promises of e-health is to enhance effectiveness in health care, therefore diminishing costs;
- enhancing quality of care- the previous feature involves not only sinking costs, but simultaneously improving quality;
- evidence based- e-health involvements should be evidence-based in a sense that their efficacy and efficiency should not be taken accepted as granted, but confirmed by rigorous scientific assessment;
- empowerment of consumers and patients- knowledge bases of medicine and personal electronic records accessible to consumers, allows a patient-centred medicine, and facilitates evidence-based patient choice;
- encouragement of a new relationship between the patient and health professional;
- education of physicians through online sources (continuing medical education) and consumers (health education, tailored preventive information for consumers);
- enabling information exchange and communication in a standardized way between health care institutions;
- extending the range of health care beyond its conventional boundaries;
- ethics- these new forms of patient-physician interaction poses new challenges and threats to ethical issues;

- equity- in spite of being one of the promises concerning e-health, the truth is that the digital divide may enhance the gap between the “haves” and “have-nots”.

However, Wyatt & Sullivan (2007) question e-health promises pointing out some pressures that the use of e-health comprise:

- patient demand- information and services can be delivered in a personalised way, where and when wanted or needed;
- new functions- it can link previously distinct services and information;
- democracy- it could let society form pressure groups, lobby for services, or even set up their own health organizations;
- health workforce- it may help with staff shortages or requests from staff for improved working lives;
- technology- futuristic devices will become more reliable, functional and cheaper;
- national policy- towards services will have an easier coordination, promoting equity and patient independence, adhering to government targets and lowering carbon dioxide emissions;
- economics- may shift some costs to the patient or into the community;
- safety- it will possibly improve personal management and avoidance of exposure to methicillin resistant *Staphylococcus aureus*.

In conclusion, e-health encompasses the need for applied ethics as suggested by Collste (2008), as well as, cross-cultural issues are a reality (see Stahl, Rogerson & Kashmeery, 2006).

Biotechnology and its applications

Contrary to its name, biotechnology is not a single technology. Rather it is a group of technologies that share two common characteristics: working with living cells and their molecules; and, having a wide range of practice uses that can improve our lives. In spite of such claim, we will plead that biotechnology is unique amongst the three major technologies for the twenty-first century- information technology, materials science, and biotechnology- in being a sustainable technology based on renewable biological resources. Such natural resources include animals, plants, yeasts, and microorganisms and have formed mankind's nascent food and beverage industry for several millennia.

So, biotechnology can be broadly defined as “using organisms or their products for commercial purposes” (National Agricultural Library, 2008). But recent developments in molecular biology have given to biotechnology a new meaning, prominence, and potential. It is (modern) biotechnology that has captured the attention of the public, which has a dramatic effect on the world economy and society.

Historically, the modern era of scientific biotechnology begins with the elucidation of the DNA structure by Watson and Crick in 1953, and the subsequent development of the tools to cleave and resplice genetic material in the early 1970s. Not surprisingly, therefore, the term biotechnology is generally considered synonymous with gene splicing and other forms of genetic engineering.

However, in the future, the most significant breakthroughs in human medicine will result from mapping and understanding the human genome. With less than five per cent of all human genes identified, it has become increasingly clear that each new gene discovery proffers new drugs for the diagnosis, treatment, and prevention of human disease. These advances will enable biotechnologists not only to measure disease potential and expand the applications for genomic diagnostics, but also to devise fundamental new therapeutic approaches. Products and medical applications of modern biotechnology include:

- artificial blood vessels- from collagen tubes coated with a layer of the anticoagulant heparin (Huynh *et al.*, 1999);
- gene therapy (altering DNA within cells in an organism to treat or cure a disease)- in order to develop therapies to treat diseases such as cystic fibrosis, AIDS and cancer (Biotechnology Industry Organization, 2008);
- genetic code tests- to understand, treat or prevent patient's diseases (examples are: carrier tests to identify genetic abnormalities that do not affect the person being tested, diagnostic tests make or confirm a diagnosis where symptoms or other indications are present, preimplantation tests can be conducted on embryos before they are transferred to the uterus in in vitro (IVF) fertilisation programs, and prenatal tests) (Verlinsky & Kuliev, 2004);
- xenotransplantation- involves the transplantation of organs, tissues, or cells from one species to another (Cooper, 1996). Of course, the aim about transplantation from animals into humans, is to fulfil the demand for transplantable organs, tissues and cells to alleviate disease and save human lives;
- human biobanks and genetic research databases- “structured resources that can be used for the purpose of genetic research, which include: a) human biological materials and/or information generated from the analysis of the same; and b) extensive associated information” (Organization for Economic Co-operation and Development, 2008, pp. 5).

Genomics and genetic engineering are also playing a substantial role in the development of agricultural biotechnology. The early goals in the development of transgenic livestock were the increase of the meat and of the production characteristics of food animals. However, long research and development timelines and low projected profit margins, especially in developed nations where food is relatively inexpensive; have shifted priorities to the production of protein pharmaceuticals and nutraceuticals in the milk of transgenic animals (Lowe, 1999). Plus, marine organisms are also capable of producing a variety of polymers, adhesives, and compounds for cosmetics and food preparation. Bioactive natural products are found in organisms that reside in areas which stretch from easily accessible intertidal zones to depths in excess of 1000 meters. Collaborations between marine chemists, molecular pharmacologists, and cell biologists have yielded an impressive library of potentially use (National Agricultural Library, 2008). However there are so many catalysts still to be discovered, which will have to exhibit improved performance, stability, turnover numbers, specificity, and product yields.

Biotechnology is also playing a role in clean manufacturing. Nevertheless, various types of chemical manufacturing, metal plating, wood preserving, and petroleum refining industries currently generate hazardous wastes, comprising volatile organics, chlorinated and petroleum hydrocarbons, solvents, and heavy metals. Bioremediation with microbial consortia is being investigated as a means of cleaning up hazardous sites. Methods include *in situ* and *ex situ* treatment of contaminated soil, groundwater, industrial wastewater, sludges, soil slurries, marine oil spills, and vapour-phase effluvia.

Finally, biotechnology is being currently used in DNA fingerprinting (process of cross matching two strands of DNA) namely into the following fields (Biotechnology Industry Organization, 2008):

- criminal investigations- DNA from samples of hair, body fluids or skin at a crime scene as a way to confirm suspects is enhancing rapidly;
- polymerase chain reaction (PCR)- process that entails into a more quick and accurate way of identify the presence of infections such as AIDS, Lyme disease and Chlamydia;

- paternity determination (another genetic test)- through DNA it is possible to confirm if a child's DNA pattern is inherited, half from the mother and half from the father;
- human fossils- to determine how closely related fossil samples are from different geographic locations and geologic areas. The results shed light on the history of human evolution and the manner in which human ancestors settled different parts of the world.

The ethical dimensions of biotechnology

The ethical issues created by biotechnology are vast and growing. Our present moral systems work mightily to reconcile the new world order into their established patterns of accepted behaviour. The ethics of biotechnology raises immensely complex issues; the biotechnology of ethics raises even more intractable ones. Our current scientific advances allow us to engineer the most basic of our life processes:

- the dissemination in our environment of genetically modified organisms (GMO);
- the genetic modifications and their use in food;
- the applications of research in human genetics.

The publication of the first experimental protocols as a technique for genetic engineering occurred in 1973 (on micro-organisms) raised the fear into researchers: many biologists considered it was a high risk activity, and therefore restrictive measures were taken. The GMOs had to be confined and prevented from disseminating in the environment. They could modify the "balance of nature" and subsequently the foreign DNA could change the metabolic activity in an unpredictable and undesirable way, producing unsuspected and irreparable damage to environment and mankind. In fact, science fiction literature was already starting the debate by presetting GMOs with the ability to destroy the reserve of raw materials, enhancing the lack of confidence concerning such organisms.

With new progress in scientific knowledge and experimental techniques, it occurred to scientists not to confine the GMOs in bioreactors, but to let these organisms grow freely in the soil in order to improve:

- the environment through micro-organisms with the ability to clean chemically contaminated soils (bioremediation);
- and, the performance of vegetal culture.

However, such decisions entail into a discussion regarding the relationships between these GMOs and other organisms (including human beings). Won't the modified characteristics be transferred to other organisms, creating non intentional and, may be, damageable effects (Organization for Economic Co-operation and Development, 2005)? Our knowledge about the interactions between the microbial populations in an ecosystem is fragmentary, especially on the exchange of genetic material, but precise studies are going on (Biotechnology Industry Organization, 2005). No negative effects of the release of GMOs (micro-organisms) have been reported until now; however studies are being conducted (Biotechnology Industry Organization, 2005). The problem is to know if they can be set up with objectivity. The question remains open: can this problem be treated with objectivity, similar to debate regarding nuclear power?

Biotechnology may soon provide us with the ultimate ability to "design" our individual moral senses and biologically "grow" implanted ethical codes of behaviour within the human being. The more commanding focus will be on the genetics of ethics, rather than on the ethics of genetics, as Backus, Spinello & Tavani (2004) demonstrate into one of the editorials of *Ethics and Information Technology Journal*, in which they introduce several papers concerning new challenging perspectives of this matter.

Therefore, we need to recognize the extraordinary uniqueness of current life forms and how highly special and precious they remain. To the extent, modern science threatens the delicate symbiosis between our ethical and legal norms and our biological evolution. New, daily scientific advances leave a moral order ill-equipped to respond. Ethical choices are the result of deeply ingrained predispositions and a lifetime of cultural adaptation. When faced with new situations, we tend to respond slowly, viewing any significant departure from the moral *status quo* as a threat. The law also inherently moves slowly, proceeding through careful analysis and studied reflection. Legal precedent and a hierarchical judicial system lend additional brakes to an already sluggish, orthodox order.

With such intrinsic conservatism, it should come as no surprise that we are today still strung along, both ethically and legally, with technological breakthroughs that are decades old. Contraception and abortion are, at their core, denials of our biological selves (Thiele, 1999) and, thus we continue to be uncomfortable with the ramifications inherent in the utilization of the technology. Contraception is still vigorously debated in many societies, through technology that is now antiquated.

Currently, biotechnology among many other things is enabling us to begin prenatal testing for fetal genetic conditions and to begin artificial manipulation of an unborn's genotype. The intractable social, moral, and legal issues posed by only these two technological advances illustrate the potential impact of biotechnology in our society (Kevles & Hood, 1993). When is such testing viable and to whom should it be made available? Which genetic disorders or diseases will allow (require?) state regulated abortions or invasive procedures? Which are the rights of a "good-gene" child to be weighed against maternal health and reproductive freedom? Who should bear the economic costs of raising a child conceived with certain knowledge of the genotype-disorder? Is there a duty for individuals to test in vitro so they may reject embryos that pose significant health costs over the embryo's lifetime? What is a "bad" gene trait and how do we decide which embryos are "good" (Burgess, 2001)? What will happen at an ethnical level: will nations be characterized by homogeneous ethnic groups, encompassing therefore synonymous cultures (Brunger & Bassett, 1998), or biological diversity will still be a reality (Lujan & Moreno, 1997)? Will equity prevail (Farrelly, 2004)? Another concern is the short shrift paid to concerns about biopiracy in isolated communities (Burgess, 2001).

Moreover, all these dilemmas entail into an important discussion regarding biotechnology patents: it is possible for a company or a country to own our genetic evolution, instead mankind itself? In fact, there is a substantial debate in public forums and academic circles about whether patenting is morally and ethically acceptable (see for example: Gold, 2000; Lever, 2001; Witke, 2005). Regarding such matter, we claim the absence of patents regarding the human genome, but also through the example given by Collste (2008) concerning the HIV patentability. Plus, allowing patents over human genetic material will create a demand for such biological materials and will increase, the likelihood that individuals will be exploited (Einsiedel & Sheremeta, 2005), and also could actually inhibit research (Earncliffe Research and Communications, 2005).

Regarding the possible ethical issues related to potential human recipients of xenotransplants once again a considerable number arise: the potential subject, a patient with end-stage organ failure, is entitled to the same rights, respect, autonomy, and voluntary informed consent that are necessary for all human subjects (Barker & Polcrack, 2001). However, it will be difficult to guarantee that xenotransplantation first patients will be truly informed given the uncertain risk analysis (Clark, 1999). There may be risks that are not yet known and which, therefore, are unable to be quantified.

Moreover, when the intention is to discuss biobanks we should pay attention to the following assumptions:

- in identified biobanks, information is stored with samples including identifiers such as patient name or number;
- in identifiable biobanks, unidentified samples can be linked back to identifiers through a coding system;
- in anonymized biobanks, samples are irreversibly stripped of all identifiers and cannot be re-linked with those identifiers;
- in anonymous biobanks, samples are collected without identifiers, therefore the source is impossible to identify.

Plus, it seems clear that the purpose of the research and the source of the genetic material affects the nature of the identification used in a given research project. In fact, The Public and Professional Policy Committee of the European Society of Human Genetics (PPPC) recommends: different approaches to ownership of samples based on the character of the collection (Ayme, 2003), and that the various approaches to ownership should be subjected to multiparty contracts rather than defined in legislation.

So, in spite of the possible differences concerning technical design it is possible to acknowledge the following common features:

- biological source material- DNA can be extracted from very small amounts of human tissue;
- genetic information systems- DNA is extracted from individual's biological material and information describing the unique characteristics of the person's genotype is stored in an electronic database;
- phenotypic information- information derived through physical examination, from questionnaires, or from individual's health records.

Given such characteristics, the World Health Organization (2003) strongly recommends the existence of a security culture concerning health data protection. Still, Gostin (2001) claims a gigantic tension between personal privacy and public good regarding such information, which will be the key future challenge for biobanks (Norwegian University of Science and Technology, 2004), being information consent a fundamental value.

Furthermore, genetic information consent is often perceived similar to general consent for research applications (Kerr, 2003); however, is well beyond those. Despite informed consent could be reduced to a simple signature, we follow McDonald (2000, pp. 304-305) that claim: "consent is a process of willing and knowing participation over time", and in biobanks due to the sensitivity of the information they hold and the potentially lengthy time that they might hold it, we may claim that information consent is a "core value":

- re-consenting- explicitly rejects the presumption that it is possible to authorize future research, stating that informed consent is only valid if participants understand the specific nature, risks and benefits of this particular research;
- blanket consent- the challenge presented by future research to informed consent can be described to research participants who can then decide whether or not to authorize that research.

Clearly, all the previous questions remind us the importance of undertaking a critical reflection concerning the role of industry into biotechnology, as Rahul Dhanda (2002) in his book, "Guiding Icarus: Merging Bioethics with Corporate Interests" explores. Dhanda makes it clear at the outset that he is an industry insider, working for Interleukin Genetics. Therefore, he is not naive about the many pitfalls of industry or the social responsibility that it bears. Even if someone disagree, as we do, Dhanda's position is very interesting concerning the following issues:

- the critical importance of comprehensive informed consent procedures- such procedures are not only hints at the real problems with how informed consent is used (as a paper to sign rather than as an ongoing process), which undermines its protective utility;
- the insufficient attention to whether DNA donors- such people are likely to understand what they are consenting to;
- the DNA databases- as it occurs in any database, DNA databases can also produce errors and be violated, which means a blind faith in them will lead people to discount the possibility that their personal DNA information can be wrong;
- the DNA patents- it should not be allowed to any company to patent the human genome, in spite of the valid economical argument concerning the costs of research.

He is still convincing about the need to integrate bioethics as a corporate value within the biotechnology industry. However, such process is drastically difficult as the survey regarding ethical practices of bioscience companies suggest (see Finegold & Moser, 2006). Therefore, the need to hire human resources with high ethical standards should be a priority, but for that is imperative that educational systems for bioengineers include the teaching of ethics as Frize (2007) advocates. To conclude, such questions guarantee many decades of ethical and legal wrangling. We are living beings designed to forward our biological selves; when technology changes the landscape too quickly, we tend to become confused and resist what are often perceived as threats to our self-identity. Technological interference with or enhancement of natural processes is, simply, something that frustrates us. And while we are attempting to resolve the momentous issues raised, technology speeds ahead leaving a perplexed and somewhat paralyzed society in its wake.

Nanotechnology and its applications

Nanotechnology emerged as an important research area in the 1980s. From the beginning, nanotechnology has been observed to be an enabling, horizontal, and cross-sectoral technology (Franks, 1987). It is projected to revolutionize several industrial sectors by providing valuable technological innovations, but before define such research field it is important to address the etymology of the concept “nano”. The Greek word *nanos* (“dwarf”) is the origin of nano; meaning that a nanometer is one billionth of a meter, or roughly 75,000 times smaller than the width of a human hair. Therefore, approximately three to six atoms can fit inside of a nanometer (nm), depending on the atom.

According to The National Science Foundation nanotechnology is: “research and technology development at the atomic, molecular or macromolecular levels, in the length scale of approximately 1-100 nanometer range” (Thibodeau, 2001, pp. 1). Or, Bonsor (2002, pp. 2) defines it “as a branch of engineering that deals with the design and manufacture of extremely small electronic circuits and mechanical devices built at the molecular level of matter”. So, the goal of nanotechnology is to be able to manipulate materials at the atomic level in order to build the smallest electromechanical devices, given the physical limitations of matter and, which we have never been able to create and observe before (Alliance for Chemical Science and Technologies in Europe, 2001). In spite of being difficult to understand such concepts, Angelucci (2001) give us an interesting analogy, which helps to enhance the comprehension regarding nanotechnology. Much in the same way that Michelangelo created statues from blocks of marble, manufacturers today frequently create objects by first creating larger objects and then removing excess material by grinding, chiseling or sanding.

When Drexler coined the word nanotechnology in the 1980s, he was discussing about building machines on the scale of molecules, a few nanometers wide-motors, robot arms, and even whole computers, far smaller than a cell (Drexler, 1986). Drexler spent the next ten

years describing and analyzing these incredible devices, and responding to accusations of science fiction. Meanwhile, mundane technology was developing the ability to build simple structures on a molecular scale. As nanotechnology became an accepted concept, the meaning of the word shifted to encompass the simpler kinds of nanometer-scale technology, as described in another book of Drexler (1991), called the “Unbounding the Future”. In fact, the importance of Drexler into the research field is also recognized through the foundation of the Foresight Institute, which is a non-profit organization dedicated to the responsible development of nanotechnology (Foresight Institute, 2000). However, this theoretical capability was envisioned in 1959 by the renowned physicist Richard Feynman in his lecture, “There’s Plenty of Room at the Bottom”, concerning miniaturization down to the atomic scale.

Applications of nanotechnology extend to several fields, following four generations of nanotechnology development (Roco, 2002; Roco, 2003). The present era, as Roco illustrates it, concerns passive nanostructures, materials designed to perform one task. The second phase, started around 2005, and introduced active nanostructures for multitasking. The third generation is expected to begin emerging around 2010 and will feature nanosystems with thousands of interacting components. After that, a few years later it will arise the first integrated nanosystems, similar to a mammalian cell with hierarchical systems within systems, are expected to be developed.

When we argue about non-linked medical applications in nanotechnology it is possible to acknowledge the following dimensions: nano-computers and defect tolerant computer architectures (Heath *et al.*, 1998). In the field of microelectronics we have the following examples: the replacement of silicon with carbon nanotubes in a transistor (McEuen, 1998); miniaturization of electronic devices (Sohn, 1998); and, DNA-based computing (Seeman, 1998). These advances have taken place with parallel advances in methodologies and instrumentation such as scanning tunneling microscopy (Quate, 1991).

Concerning the analytical aim, examples of nanotechnology generations in biomedical and biotechnology are: targeted drug delivery, gene therapy, and nanomedicine (biomechatronic human prostheses for locomotion, manipulation, vision, sensing, and other functions, such as: artificial limbs, artificial internal organs, artificial senses, human augmentation) (Bogunia-Kubik & Sugisaka, 2002). This field has important connection with neuroscience, to develop neural interfaces and sensory motor coordination systems for the integration of these bionics devices to human body/brain. However, given the nature of our contribution we will approach the major medical applications concerning nanomedicine:

- thermotherapy;
- photodynamic therapy;
- chemotherapy;
- radiotherapy.

Hyperthermia therapy is based on the fact that tumour cells are more sensitive to temperature increase than normal tissue cells (Cavaliere *et al.*, 1967). The most common processes are: photo-thermal ablation therapy using silica nanoshells (Hirsch *et al.*, 2003); photo-thermal ablation therapy using carbon nanotubes for selective tumour cell destruction without harming normal cells *in vitro* (Kam *et al.*, 2005); magnetic field-induced thermotherapy using magnetic nanoparticles (Jordan *et al.*, 2001).

Photodynamic therapy is an emerging treatment modality where a light-sensitive molecule or photosensitizer exposed to visible or near-infrared light induces cytotoxic effects in the presence of oxygen. Photodynamic therapy can be used to treat a variety of oncological, cardiovascular, dermatological, ophthalmic, and immunological disorders (Trauner & Hasan, 1996), and existing two major processes: quantum dots as photosensitizers and carriers

(Dubertret *et al.*, 2002); and, ceramic-based nanoparticles as carriers (Yan & Kopelman, 2003).

Chemotherapy is another emergent treatment for cancer which has three different medical applications: nano-structured polymer capsules (Radt *et al.*, 2004); dendrimers (Li *et al.*, 2003); and, nanocells (Semenza, 2000). Finally, radiotherapy can be characterized as an experimental approach to cancer treatment, as is supported by the following techniques: dendrimers for boron neutron capture therapy (Barth *et al.*, 1994); carbon nanotubes for boron neutron capture therapy (Yinghuai *et al.*, 2005); and, gold nanoparticles (Hainfeld *et al.*, 2004).

Finally an important question arises: why is the length scale of nanotechnology so important? According to the Los Alamos National Laboratory (2008), there are five reasons:

- the wavelike properties of electrons inside matter are influenced by variations on the nanometer scale. By patterning matter on the nanometer length scale, it is possible to vary fundamental properties of materials without changing their chemical composition;
- the systematic organization of matter on the nanometer length scale is a key feature of biological systems;
- nanoscale components have very high surface areas, making them ideal for use in composite materials, reacting systems, drug delivery, and energy storage;
- the finite size of material entities, as compared to the molecular scale, determine an increase of the relative importance of surface tension and local electromagnetic effects, making nanostructured materials harder and less brittle;
- the interaction wavelength scales of various external wave phenomena become comparable to the material entity size, making materials suitable for various opto-electronic applications.

The ethical dimensions of nanotechnology

With such fearful dangers inherent in nanotechnology, we have to seriously analyze its potential consequences. Granted, nanotechnology may never become as powerful and prolific as envisioned by its evangelists, but as with any potential, near-horizon technology, we should go through the exercise of formulating solutions to potential ethical issues before the technology is irreversibly adopted by society. We must inspect the ethics of developing nanotechnology and create policies that will aid in its development so as to eliminate or at least minimize its damaging effects on society (Sweeney, Seal & Vaidyanathan, 2003). However, the ethical implications of nanotechnology are simultaneously unpredictable and predictable.

In his novel *The Nanotech Chronicles*, Michael Flynn (1991) presents his view on the gradual development of future nanotechnology and its social implications throughout six nano-science fiction stories, which can provide us some interesting directions regarding such matter. However, we tend to ignore that the ethical perception concerning biotechnology can be a good starting point for the ethical implications of nanotechnology, as suggested by Weil (2001), or Wolfson (2003). Moreover, the principles that Richard Severson (1997) outlines in his book, “*The Principles of Information Ethics*”, to guide IT ethical decisions are also insufficient to this analysis. In our opinion, the ethical analysis concerning nanotechnology should engage the implications link between:

- individual level;
- professional level;
- and, societal level.

Nanotechnology as a tremendous impact on individual identity because the ethical concept of life revolves around nanotechnology in accordance to Venneri (2003, pp. 234):

“nanotechnology encompasses the attributes of self-generation, reproduction, self-assembly, self-repair and natural adaptation”, and clearly these are all attributes we ascribe to living things. The other, less prodigious aspect of how the concept of life might change with nanotechnology regards the promises of nanomedicine. Nanotechnology may be able to repair or reproduce tissue, diagnose disease (e.g. cancer) at a very early stage, dispense drugs at the cellular level, and even reverse diseases. Therefore, our concept of the human life span may be revolutionized as a result; people may live longer by techniques considered by many as artificial. Some will wonder if nanotechnologists are “playing God” by tinkering so directly with nature. Others will wonder to what extent humanity and nanomachinery will blend; if we are downloaded into our technology, what are the chances that we will thereafter be ourselves or even human (Weckert, 2001)?

Plus, future nanotechnology-enabled, implanted or swallowed diagnostic tools will make possible the collection of an enormous amount of individual cellular/subcellular level surveillance data of the human body, which is remotely transmitted to a medical database server to be analyzed and monitored by a diagnostic software. If and when such technologies become possible, a crucial ethical question arises: can the health information infrastructure handle, collect, process, and analyze real-time on-going health data? Moreover, ensuring privacy and confidentiality in such a system would be of utmost importance; a system without adequate safeguards presents serious ethical problems.

From the above, it is clear that an in-depth ethical analysis must fulfil the following requirements in order to achieve human dignity (United Nations Educational, Scientific and Cultural Organization, 2006):

- non-instrumentalisation- the ethical requirement of not using individuals merely as a means but always as an end of their own;
- privacy- the ethical principle of not invading a person’s right to privacy;
- non-discrimination- people deserve equal treatment, unless there are reasons that justify difference in treatment. It is a widely accepted principle and in this context it primarily relates to the distribution of health care resources;
- informed consent- the ethical principle that patients are not exposed to treatment or research without their free and informed consent;
- equity- the ethical principle that everybody should have fair access to the benefits under consideration;
- the precautionary principle- this principle entails the moral duty of continuous risk assessment with regard to the not fully foreseeable impact of new technologies as in the case of ICT implants in the human body.

At a professional level nanotechnology can raise the following issues to its practitioners (Flynn, 1991):

- the dimensions of intended and unintended social consequences of technological innovation, including attempts to fix unintended consequences by technological implementation, and cultural conservatism;
- understand the limits of social foresight and of planning technology-induced social changes;
- the different kinds of interests and values that professionals are confronted and the need for responsible decisions;
- risk analysis and the social relativity of risk perception;
- standard excuses from moral responsibility.

Finally, at a societal level we may refer that nanotechnology embraces potential dangerous for the environment. In 2002, researchers reported to the Environmental Protection Agency (EPA) that nanoparticles have appeared in the livers of research animals and that there is a potential for nanoparticles to piggyback on bacteria and enter the food chain. There is no regulatory body that is tracking nanomaterials, so we could be releasing an undetectable toxin into the biosphere (Rupley, 2002). However, the ethical dilemmas are far more complex rather than environmental issues.

An essential feature that sets nanostructures apart from other artefacts is size. They are from 1 to 100 nanometers, from one- to 100-billionths of a meter, significantly less than the 50,000 nanometers of a human hair. Obviously, they cannot be perceived by the naked eye (Ratner, 2003, pp. 6), and can thus be produced and deployed without ever being observed by any human being. The kinds of ethical issues this unobservability creates can be illustrated by noting three problems: privacy; intrusion; disclosure and appropriation. These problems are external to nanotechnology. They arise through what are predictably the ordinary uses made of nanostructures or, as a consequence of being nanostructures at all.

Concerning privacy, we could simply add nano-sensing devices to the paint or a composition floor to turn a 'safe' room into a recording and transmitting studio. Alternatively, such devices could be put into our bodies without knowing. The average citizen would be at the complete mercy of anyone familiar with nano-sensing. Their detection would require what we can presume to be special highly sophisticated equipment (Robison, 1994).

We are also helpless to preclude disclosure, the second privacy tort. The standard sort of example is someone's passing on a secret. The secret is disclosed. We all keep some information to ourselves. This is, among other things, one way of distinguishing between friends, acquaintances and strangers. We tell friends things about ourselves that would be inappropriate to tell our acquaintances (although that would be one way of beginning to turn an acquaintance into a friend). Telling such things to strangers would mark us as addled, if not crazy. Control over information about our personal lives allows us to keep, among other things, control over who we are: publicly, and privately. Nanosensors would allow a stranger to know everything about us that we would want to control, from private conversations with one's spouse or lover to intimate details about one's body temperature and state of health. A stranger could well know far more about us than we can know about ourselves (Robinson, 2004). That someone knows as much or more about us as we do concerns the last relevant privacy tort, namely appropriation. That occurs when someone takes another's identity. Such theft will become as easy as information about us is relayed to a stranger who will pick up all those conversations we think are private, and use that information to appropriate our identity (Robinson, 2004). In each case- intrusion, disclosure and appropriation- our privacy is invaded, and of course such invasion can obviously also be harmful.

Focus

Bionanotechnology and its applications

After debating biotechnology and nanotechnology, how can we define bionanotechnology as a research field? Presently, a lack of consensus concerning such concept is a reality. However, to take advantage of the enthusiasm of funding agencies, a number of old (and important) areas, such as colloid science, molecular biology, and implantable materials surface science, have been relabeled nanotechnology. In fact, all of these fields coupled with biological systems, should be included in bionanotechnology. Therefore, the idea of bionanotechnology embraces engineering interfaces between molecules or materials and biological systems, which clearly involve a wider, or a blurred definition.

Even acknowledging the following definitions the quandary holds: “bionanotechnology claims that it is a multi-disciplinary area that sits at the interface between engineering and the biological and physical sciences” (Biotechnology and Biological Sciences Research Council, 2007, pp. 1); while the Organization for Economic Co-operation and Development defines it as “an area that covers the interface between physics, biology, chemistry and the engineering sciences” (Organization for Economic Co-operation and Development, 2005, pp. 4); or, “bionanotechnology represents the convergence of nanotechnology and biotechnology, yielding materials and products that use biological molecules in their construction or are designed to affect biological systems”(North Carolina Biotechnology Center, 2007, pp. 3). Referring the non-linked applications to e-health it is possible to point out the following ones: engineering biomolecules for non-biological use, such as DNA-based computer circuits using nanotechnology tools. As linked applications to e-health literature acknowledges the following ones: nanomaterials with biological systems for outcomes such as targeted drug therapies, nanobiological materials for human body enhancement. However, despite the political rhetoric and normative discourses that claim the prospective of such technology, due to immeasurable institutional inflexibility (insecure career paths, unfair evaluation, need of longer training), the truth is that the conventional wisdom concerning its benefits is not supported by systematic evidence and remains poorly understood (Schild & Sorlin, 2005). Although since the 1990s there has been an outstanding output of new empirical studies to add to the more plentiful conceptual and normative approaches adopted in the past, there is a worrying lack of consensus even about how to measure cross-disciplinarity (Bordons, Morillo & Gómes, 2004). Another crucial aspect that still needs to be evaluated is the costs and risks of failure regarding its ethical and moral dilemmas.

Technological example

A practical application of bionano materials will be the possibility to replace cells or molecules when a serious traumatic injury affects your body. In the Department of Chemistry at Johns Hopkins University researchers have found through the observation of Alzheimer’s patient’s tissue, that is composed by plaques made from very small fibbers (Institute for Nanobiotechnology, 2008). These fibbers are very, very long and narrow; however, they perfectly match when combined or reproduced.

At this point, we need to approach the concept of severe traumatic injury in a medical sense: body or emotional injury resulting from physical or mental wound or shock. A traumatic injury is caused by something outside the person's body as opposed to a sickness or a disease. An example would be injury to a hand that is smashed in a machine, a car accident that lead to a severe damage into your spinal cord, or still a nervous breakdown caused by stress on the job (Medical Dictionary, 2003). When a traumatic injury occur communication between nerve cells is lost, because the flux of electrical signs is interrupted. So, these bionano materials with the ability to reproduce themselves will allow re-establishing communication between such cells, because they are a combination of semiconductor (electronics carbon based) and organic (biological tissue) parts.

However to establish a bound between such technology and telemedicine we need to approach the proceeding method between the medical application and doctor’s medical guidance. We can distinguish two levels of analysis:

- the communicational act between patient and doctor;
- and, the new technological capabilities that these applications will provide to medical staff.

The communicational process embraces two different perspectives to this kind of treatment: remote application if only a traumatic injury happens, or the introduction of such treatment as

a “vaccine” into the human body allowing immediate treatment after such injury. Despite the possible choice, if the bionanorobots intervene due to a traumatic injury communication is immediately established, allowing that medical staff monitor the process and compare the data collected with the existing one. Furthermore, the technological capabilities that are bounded to such treatments are: Virtual Reality and telematic. Virtual Reality not only provides immersive visualization, but also gives an added functionality of *navigation* and *interactive manipulation* of molecular graphical objects. Plus, it also provides the opportunity to medical staff to experience the perception and interaction with our body, given the 3D image environment. Telematic will make possible to remote the system with feedback through sensors, which engages different reactions depending on the type of material the operator is dealing with, and imitation tools at the workstation corresponding to the actual tools of nanorobots.

Concluding, it is clear that such medical applications embrace a wide range of ethical issues, which will be under debate into the following section.

The ethical dimensions of bionanotechnology

Given the previous sections human body enhancement is the main feature concerning bionanotechnology medical applications. If we are incorporating computer chips into our body, it could be understood as a violation of “natural” boundaries? Should we develop devices that interact directly with the brain, or that exert internal or external controls over bodily and mental functions? What effect would a neurotransplant have on humans, and in what extent will we be responsible for our actions? What is the relationship between one’s identity and one’s body? At this point, it is unfeasible to know the outcome of such answers, but we should discuss the concept of enhancement, as well as its ethics.

Enhancement is in its essence improving or adds new capacities to the human body. In spite of its concise definition, it is defined as an ambiguous concept which can mean better and more, but also something that most people may think to be less desirable and that should be avoided. The negative evaluation of enhancement appears in the first half of last century due to the appearance of *eugenics*. However, the difference seems to rely on the “old” eugenics versus the “new” eugenics on free choice and autonomy (*liberal eugenics*) (Agar 2004). Nonetheless, the basic idea is the same, namely the wielding out of undesirable physical and psychological traits.

In order to get a better understanding of the moral value of enhancement, we need to discuss the concept of therapy. Therapy concerning enhancement technology is often seen as something “good”, while enhancement is frequently something negative. Such answer is related to the medical paradigm, and even if drawing a sharp line between therapy and enhancement was possible, we would still face the problem of knowing what counts as an enhancement. In order to diminish the lack of uncertainty, we plead three arguments that describe an enhancement in spite of the potential critics that possibly will arise due to the individual notion of human limits or limitations (see for example, Nordmann, 2007):

- certainty- the physical, psychological and cognitive characteristics of the human body are enhanced;
- consistency- the outcome of such “biological manipulation” is similar to an “environmental manipulation”. There is no relevant moral difference between them;
- similarity- if we accept treatment and disease prevention, we should accept enhancement. The goodness of health is what drives a moral obligation to treat or prevent disease.

To debate the ethics of enhancement we will focus our attention on the following authors:

- Kass and Fukayama- do not endanger human nature;

- Habermas- on enhancement and moral status;
- Sandel- enhancement as a threat to central human goods.

Despite countless discrepancies in their analysis, Leon Kass and Francis Fukuyama both warn that biomedical interventions aimed at enhancement might destroy human nature (Fukuyama, 2002; Kass, 2001). Both could be interpreted as providing an anti-enhancement, because they assume that the destruction of human nature would be so terrible that excludes, or at least clearly outweighs any reasons in favor of doing that which threatens such destruction. In our opinion such claim tends to fail because for example Blake (2007) pleads the idea that the future does not humans which contradicts the criticism concerning enhancement through biomedical applications.

Moreover, Habermas (2003) consider that this sort of enhancement violates the principle of equity dictating people as free beings. He also apparently, believes that something violating this fundamental principle maybe a conclusive reason for avoiding it, not merely as a reason against it, but against reasons in favour of it. So, Habermas (2003) argues that any consideration in favour of genetic engineering enhancements should be irrelevant.

Finally, Sandel's disagreement against enhancement is that the effort to enhance human beings both expresses morally flawed attitudes and undermines virtuous ones. Sandel claims that those who pursue enhancement act as a boundless craving for "mastery" and thereby contribute to erosion, in themselves and others, of the sense of "the giftedness." The sense of "giftedness," according to Sandel, includes an acceptance of the limitations of human powers and "openness" to what we cannot control and, it is a precondition for having proper humility and perhaps other virtues as well. So, Sandel consider that the sense of "giftedness" is or is necessary for fundamental human goods and that biomedical enhancement endangers it (Sandel, 2002). However, it seems to us that the argument introduced by Sandel (2002) seems to not fulfil a conclusive reasoning for forgoing biomedical enhancements. In fact, the main assumptions of Sandel can be outlined as follows:

- the sense of the giftedness is a central human good;
- the drive for mastery is incompatible with the sense of giftedness.;
- the employment of biomedical enhancements is an instance of the drive for mastery;
- therefore, the employment of biomedical enhancements is incompatible with the sense of giftedness.

In conclusion, it is clear that such discussion is an ongoing dialectic process that entails into a personal view about the concept of human being and its limits or boundaries.

Future Trends

To promote an insight perspective considering future trends of these domains we acknowledge the need for a "holistic human project" that could bring together the best research clinicians, biomedical engineers, biomedical scientists, nanotechnologists, and others, because the great convergence that is taking place today should not be mistaken with the mundane growth of interdisciplinary or multidisciplinary fields. The aim of such project should be a continuous discussion concerning life-shortening diseases and conditions versus current progress or problems in their treatment or eradication, because as Miller stated in 1969, such circumstances would be possible to achieve through the "continuously monitorization by modern instrumentation of the physiological function" (pp. 443-444). However, public trust in science cannot be achieved without an open and transparent communication about the potential or perceived risks associated with the technology, because

as Jesús Mosterín (2002) emphasizes: technology itself is ethically neutral, and its impact depends on how it is used. In spite of such claim, we also agree with the critique claimed by Horner (2007), concerning the ability to forecast ethics existence based on the argument of generational choice. The truth is that ethical issues emerge if the development of new technologies or their prospective products conflicts with a society's ethical standards. While governments and institutions' cannot control the ethical standards of their society, they are required to minimize the conflict, using four ways:

- enacting regulations to protect people from risks;
- supporting research to provide necessary knowledge concerning the stakeholders decision-making;
- educating the public on the various pros and cons of the technology in question to enable educated public technology assessment;
- and involving citizens in technology governance to increase the conflicts.

Given the complex and global nature of our focus, the truth is that concerning regulations the United Nations should convene an international conference with a view to the creation of a permanent international multi-stakeholder body to review, monitor and regulate developments. There is as much reason to create such a body as there was to create the International Atomic Energy Agency with its monitoring powers.

In accordance to Varvasovszky & Brugha (2000), a stakeholder analysis is an approach, a tool or set of tools to generate knowledge about players so as, to understand their behaviour, intentions, interrelations and interests. For assessing the influence and resources they bring to bear on decision-making or implementation processes. A stakeholder, in this context, is any organization, individual, or entity that is involved with or, can stand to gain or lose in a certain venture. However, throughout literature it is possible to acknowledge scarcity concerning the identification of the stakeholders, because generally such analysis is named by societal debate. Plus, none actually demonstrate a concrete methodology for performing a stakeholder analysis on such research fields, and the four key steps that characterize traditional stakeholder analysis:

- identify the stakeholders involved;
- identify the stakeholders' views on, and stake in;
- assess stakeholder interest in or influence over the issue;
- and, create strategies to deal with the problems a multitude of stakeholders with different stakes.

Do not respond in an effective way to the quoted challenges. Moreover, one of the purposes of educating the public is to allow that citizens feel more comfortable concerning the development of new technologies. The main issue is to provide accurate and balanced information which citizens think they needed in order to, decide whether technologies constitute or not a significant risk. However, an underlying issue may be a lack of knowledge about the processes of conducting scientific research and developing new technologies, and a naive understanding of how risk is assessed and regulations constructed. All these issues must be clarified, framed and explained to citizens, in order to reduce their frustration, and even change their opinion).

Finally, involving citizens in technology governance will allow a continuous dialectic approach to moral, social, legal and ethical behaviours, as for example concerning the following issues (Wickramasinghe, Choudhary & Geisler, 2007):

- will we be able to differentiate such technologies?;
- where will we stop?;

- will genetic modifications that increase sustainability breach our current definition of being “human”?.

So, such governance will allow conflicts ameliorating.

Conclusion

Throughout this contribution we have acknowledged the arguments that allow us to reveal the answers to the sub research questions. Plus, we were able to respond to the primary research question: how can we define bionanotechnology as a research field? However, the sub-research questions that derive from such field remain answered.

In our opinion, bionanotechnology encompasses not only the ethical dilemmas that prevail in each, biotechnology and nanotechnology research fields, but enhanced such dilemmas. The main reason for our argument is simple, and probably debatable; however, we introduce two valid assumptions in order to justify it:

- bionanotechnology as a research field is still an unknown variable, as well as its boundaries. In fact, even the scientific community disagree about the concept itself (see bionanotechnology and its applications);
- the ethical and moral dilemmas engaged by biotechnology are still under debate, and may be considered blurred or fuzzy. Therefore, the ethical and moral dilemmas of bionanotechnology can be classified as even more blurry or fuzzy, which is illustrated by the absence/reduced of literature regarding such matter;

In conclusion, because bionanotechnology is still in its childish phase this paper “draw” a broad picture of social and philosophical claims on the developing research field/technology, and of the array of ethical dilemmas. Plus, it is proved that there are already sufficient questions to deserve in-depth studies. Among the most important applications, particularly in the context of medicine, are human enhancement, human-machine interfaces, information and complexity in relation to nanodiagnosics, unintended consequences of targeted therapeutics, diversion to other fields outside medicine, and the social and ethical priorities towards which these technologies should be steered.

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Key Terms

Bionanotechnology- multidisciplinary research field that represents a convergence between engineering, biological sciences, physical sciences and ICT.

Biotechnology- the use of organisms or their products for commercial purposes.

E-health- the use of modern ICT to meet needs of citizens, patients, healthcare professionals, healthcare providers, as well as policy makers.

Ethical dilemma- is a circumstance that often involves an apparent conflict between moral imperatives, in which to obey one would result in transgressing another.

Health- a combination of the absence of illness, the ability to cope with everyday activities, physical fitness and high quality of life.

Healthcare- prevention, treatment and management of illness through the services offered by the medical, nursing and allied health professions.

ICT- a range of technologies for gathering, storing, retrieving, processing, analysing, transmitting and receiving information.

Moral dilemma- when an agent has moral reasons to do each of two actions, but doing both actions is not possible.

Nanotechnology- creation of functional materials, devices and systems through control of matter on the nanometer length scale, as well as, their exploitation.

Telemedicine- the delivery of healthcare and information across distance through the use of ICT.