

Nothing New (Ethically) Under the Sun: Policy & Clinical Implications of Nanomedicine

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Résumé

La recherche en nanotechnologie commence à recevoir une attention croissante dans les médias et la littérature de vulgarisation scientifique, mais les discussions sur les espoirs et les craintes concernant les nanotechnologies sont déjà polarisées par des visions utopiques et dystopiques. Par ailleurs, certaines discussions plus modérées se concentrent sur les applications à court terme des nanotechnologies, ainsi que sur leurs avantages et désavantages potentiels. Cependant, en explorant les implications sociales et éthiques des nanotechnologies (ou la nanomédecine, le but du présent document), d'importantes leçons devraient être tirées des expériences dans d'autres domaines. En particulier, les études sur les enjeux éthiques, légaux et sociaux (ELSI) de la recherche en génétique ont réussi à cartographier un grand nombre des questions (et des réponses sociales et politiques) qui se posent lorsque de nouvelles technologies sont déployées. Nous soutenons que, pour la plupart, les questions éthiques et sociales qui se posent dans la nanomédecine ne sont pas tout à fait nouvelles et ne nécessitent donc pas de nouveaux principes ou cadres éthiques, ni un investissement massif dans la recherche « NELSI ». Au lieu de cela, nous avons besoin d'un soutien pour le développement d'une *culture de l'éthique* parmi les scientifiques et les cliniciens, des connaissances de base en science et médecine pour les bioéthiciens et une compétence sociale pour les citoyens pour qu'ils puissent participer activement aux débats sur les répercussions des nouvelles technologies en général.

Mots clés

Nanotechnologies, éthique, financement de recherche, ELSI, politique

Abstract

Nanotechnology research is beginning to see widespread coverage in the media and popular science literatures, but discussions of hopes and fears about nanotechnology have already become polarised into utopian and dystopian visions. More moderate discussions focus on the near-term applications of nanotechnologies, and on potential benefits and harms. However, in exploring the social and ethical implications of nanotechnology (or nanomedicine, the focus of this paper), important lessons should be learned from experiences in other fields. In particular, studies of the ethical, legal, and social issues (ELSI) of genetics research have successfully mapped out many of the issues (and social and political responses) that arise when new technologies are deployed. It is our contention that, for the most part, the ethical and social issues arising in nanomedicine are not altogether new, and thus do not require novel ethical principles or frameworks, nor a massive investment in 'NELSI' research. Instead, what is needed is support for the development of a *culture of ethics* amongst scientists and clinicians, basic scientific and medical knowledge for bioethicists, and a social competency for citizens to participate actively in debates about the implications of new technologies in general.

Keywords

Nanotechnology, ethics, research funding, ELSI, policy

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Conflicts of Interest

Bryn Williams-Jones is the Editor-in-chief of the Journal; he has co-authored with Charles Dupras, supervised the PhD of Jason Behrmann, and currently supervises Ali Okhowat.

Introduction

The last decade has been characterized by increasing hype about nanotechnology and nanomedicine, often in the form of scientific and governmental exuberance about the potential clinical (and economic) benefits. The ability to manipulate materials at the atomic or nanoscale – whether they be physical (e.g., metals), chemical (e.g., polymers) or biological (e.g., DNA) in nature – has enabled scientists to access special properties associated with quantum mechanics (e.g., greater surface area, chemical reactivity) and develop new materials or systems. But the very thing that makes nanotechnologies desirable can also limit our understanding of how these properties may interact with other materials and systems at the nano or macro scales. The enthusiasm for “all things nano” has thus been matched by mounting concern on the part of activists and social commentators about the safety of nanotech-derived products and their impact on public health (e.g., pollutants or mutagens), and the potential social and ethical issues (e.g., use for enhancement or military applications). Countless stories in the print, television, and radio news have both enthused about the possibilities and lamented the dangers of nanotechnology. Similarly, in the academic literature, health science research published in journals as diverse as *Biomedical Microdevices* [1], *Mycopathologia* [2], *Nanotechnology* [3], and *BMJ* [4] has pointed to both the potential health benefits and risks associated with nanomedicine. On the ethical, legal, and social side, we have seen articles published in *Technology Review* [5] *Columbia Science and Technology Law Review* [6] and *Nanotechnology* [7], and these have focused more on the particular challenges raised by nanomedicine for individuals, institutions and society.

Much like the early debates about genetically modified foods in the late 1990s [8], discussions about nanotechnology have also been characterised by utopian and dystopian visions of the future [9-11]. Between these extremes, discussion has centred on the impact that the anticipated breakthroughs in nanoscience and nanotechnology will have upon existing chemical, material, biological and information sciences. In the case of biology and medicine, which are the focus of this paper, research points towards new means of circumventing problems faced by gene therapy and current methods of drug delivery, to name but two examples [12-14] But as is

the case with many forms of scientific research and innovation, applications of nanomedicine will not be without risks. Nanoparticles may target the wrong cells or interact negatively with the body's proteins, enzymes, or organs; worse yet would be the uncontrolled replication of nanoparticles, potentially resulting in leukaemia-like phenomena similar to what has occurred with some viral-based gene therapy experiments [15,16]. Beyond the context of human health, nanotechnology innovations may raise concerns about the environment (e.g., risks of widespread contamination), regulatory issues (e.g., regulating in a context of significant scientific uncertainty about risk), privacy [17] and civil liberties (e.g., potential for low-cost and thus pervasive surveillance), military applications (e.g., nanoscale weapons), etc. [18].

In seeking to understand the challenges posed by developments in nanomedicine, we suggest that important lessons can and should be learned from research and policy on the ethical, legal, and social implications of genetics/genomics research, known as ELSI in the US and GE3LS (Genomics, ethics, environment, economic, legal issues) in Canada. As with nanotech, early developments in genetics (and then genomics) led to much scientific, policy and media hype, which was closely followed by public and academic concerns about health and safety issues, as well as social and ethical challenges that needed attention (e.g., stigmatization, discrimination, designer babies). Two decades of ELSI research helped shape the development and implementation of genetic and genomic technologies, resulting in vigorous debate about and the production of a plethora of ethical frameworks and public policy on everything from informed consent regarding biobanking [19] to the direct-to-consumer marketing of genetic tests and other 'personalised medicines' [20].

In line with other commentators [21], it is our contention that, for the most part, the socio-ethical and legal challenges or questions posed by nanomedicine are not altogether new or very different from those identified with genetics or genomics technologies. Such being the case, they do not *necessarily* require novel ethical frameworks nor a massive financial investment in 'NELSI' research because most of the ethical principles or tools needed to address the challenges posed by nanotechnology already exist, having been developed during three decades of ELSI research. What is needed, instead, is support for interdisciplinary collaborations between applied (nano)science and ELSI researchers to address problems related to nanotech as they arise [22], in order to develop a *culture of ethics* amongst scientists and clinicians, and ensure that bioethicists (and other humanities and social sciences scholars) have sufficient understanding of the basics of science and medicine. But it will also be important to help the public develop a broader public or social competency – i.e., basic scientific knowledge and critical thinking skills – so that citizens can be equipped to engage with debates about the implications of new technologies in general.

Lessons from the World of Biotechnology and Genetic Engineering

Well before the completion of the Human Genome Project in 2003, a substantial body of academic and policy literature had developed, replete with stories of hope, hype, and fear about the near term benefits and harms of genetics and genomics research. Within a decade, it was promised, genetic testing and gene therapy would cure both rare and common diseases, and pharmacogenomics (i.e., understanding the influence of genetic variation on drug response) would revolutionise pharmaceutical development, drug delivery, and usher in a future of cost-effective personalised medicine [23,24]. But these hopes have proven premature. Gene therapy research, while showing some promise in the development of safe and effective delivery mechanisms, has been marred by very public setbacks including the deaths of research subjects [25], while in the case of pharmacogenomics, even putative exemplars of the

technology (e.g., Herceptin and Abacavir) have been of limited efficacy [26,27]. Cautious evaluations suggest that while there may eventually be practical applications of these technologies, they are unlikely to be 'just around the corner' [28]. More vocal opponents argue that the public has been misled, and that the primary goals of massive government investments in the Human Genome Project and biotechnology had more to do with supporting 'big science' in pursuit of economic development and the creation of 'knowledge-based economies', than with improving human health [29]. This is not to say that genetics research is a hopeless endeavour, only that the development of practical applications will take longer, and be much less predictable, than was initially promised [30].

It appears that with nanotechnology, history is to some extent repeating itself. The pattern of two-lane hype – glowing scientific optimism coupled with strident social criticism – is strikingly similar to the pattern so recently observed in relation to biotechnology [31]. However, hype has its upside and its downside. While hype may be crucial for attracting initial research funding and sustaining scientific, government and public support, if overdone, hype can create unrealistic expectations that could lead to a loss of public trust [32-34]. However, empirical research is still needed to see whether this loss of trust actually occurs in practice, and with which technologies [35]. Similarly, over-sensitivity to or disproportionate concern about particular technologies can lead to their implementation being significantly delayed or unduly constrained. A case in point was the focus on the human safety issues with GMO foods, which received considerable public attention despite a lack of scientific evidence to substantiate such risks. The misguided focus on human health and the related debate over the labelling of GM foods arguably shifted public attention away from more plausible concerns related to the environmental impact of GM crops [36]. In a context where there is significant scientific uncertainty about the safety of a new innovation, a precautionary approach is fully justified and warranted to ensure the protection of public health and security. Our point, here, is that an overly hyped or polarised public debate about a class of technologies – such as GMOs, or for our purposes, nanotech – can lead to an entire sector being inappropriately "painted with the same brush", thereby undermining the deployment of certain beneficial and safe innovations while also minimizing regulatory controls for those innovations that are clearly problematic.

The events of the last two decades – with 'hyped' biotech and genetic innovations being accompanied by substantial public and academic debate over associated ethical, legal and social implications – are, we suggest, being repeated in the case of nanotechnology. Putting aside the more extreme concerns about environmental disaster, expressed most dramatically by Prince Charles' fear of self-replicating nanorobots running amok and leading to a world overrun with "grey goo" [37], there are legitimate questions about the safety of some nanotech developments (including questions about pollution and toxicity) because of scientific uncertainty about how nanoparticles interact with biological systems (e.g., human lungs). But while the particular properties and behaviour of nanoparticles clearly require scientific study in order to determine when and how they might be toxic and thus in need of control (e.g., health and safety regulations), this does not mean that an entirely new field of environmental or health sciences is required with completely new tools or infrastructure. Like early reflections on the ethical, legal and social implications (ELSI) of genetic technologies, initial work on the ethics of nanotechnology seems to assume that 'this stuff is radically new,' requiring a 'new ethics' because the existing ethical or conceptual tools are insufficient [38]. The difference, however, is that nanotech ethics, or NELSI, is developing in a context where there is already a well established field of research, i.e., ELSI. It is important, then, for NELSI researchers to be modest in their calls for support and attention to issues of legitimate concern in nanotech, and

not to oversell their speciality as if it is an entirely new field, in need of completely new resources.

More Smoke than Fire?

Developments in genetics and biotechnology in the 1980s and 1990s led to substantial international political, academic, and financial investment (US\$100 million invested by the US government alone) in ELSI research [39]. Faced with novel technologies and medical procedures such as predictive testing for late-onset conditions, genetic testing for characteristics and for variations between population groups, and embryonic procedures, it was deemed critical to also consider the range of attendant social and ethical questions [40]. Indeed, ELSI research has gone a long way toward addressing many of these questions and supporting the implementation of national and international policies and regulations to minimize and control potential harms. For example, international and professional moratoria have been implemented to protect against unjust discrimination in the use of genetic testing for health or life insurance [20,41], and to prevent the genetic modification of germ-line tissues in face of the grave misgivings concerning the genetic engineering of future generations [42]. These moves arguably resulted in large part from a willingness of researchers to engage in multi- or interdisciplinary discussions, and so one of the real accomplishments of ELSI has been to bring together diverse research communities. However, ELSI research has also been criticized for being complacent about (if not complicit in) dominant social and political ideologies, and insufficiently responsive to public concerns and the need for greater democratic involvement [29,43]. Further, the focus of much ELSI research has been on the implications of a narrow group of technologies (e.g., genetic tests, new reproductive technologies, stem cell research) [44] and so has not given adequate consideration to the larger social and political contexts in which these technologies manifest [45].

In light of both the strengths and weaknesses of ELSI, we should be cautious about calls for similar large-scale public investment in nanotechnology ethics, such as the US 'NELSI' programme, or as Mnyusiwalla, Daar and Singer propose for the Canadian context, 'NE³LS', the study of nanotechnology's ethical, environmental, economic, legal, and social implications [7]. According to these authors, "what is worrying...is that the serious study of NE³LS research lags far behind the science. Despite availability of research funds, NE³LS research has not yet been taken seriously and pursued on a large enough scale" [7, p. R9]. This concern, however, seems to play on the naïve view that science and technology develop in a vacuum, outside existing social, ethical and political discourses; and thus according to Mnyusiwalla *et al*, nanotechnology can be seen to 'race ahead' of the ethics because the 'ethical issues' are specific to the individual technology in question. Yet, as has been clearly demonstrated in the science and technology studies literature, technologies are invariably developed within and responsive to the larger social, political and cultural contexts, including socio-ethical debate [46-48]. We agree with Mnyusiwalla *et al*. that nanotechnologies present important social and ethical challenges in need of critical study, such as the implications for privacy and civil liberties of the convergence between hitherto distinct technologies (telecommunication, computing, optics). Nonetheless, we maintain that many – if not most – of the social, ethical and legal concerns related to this technology, and in particularly those that relate to novel medicines, are similar to those arising with other new biomedical technologies, and for which we already have a set of tried and tested ethical tools, including principles and ethics frameworks.

Ethics and Nanomedicine

Nanomedicine might be thought to be categorically different from biotechnology because it is inherently interconnected to the broader field of nanotechnology, a field that integrates or leads to the convergence of domains as diverse as biology, material sciences, chemistry, particle physics, public health and environmental science. In other words, the socio-ethical issues associated with nanomedicine will necessarily include considerations of public health, environmental impact, and so on. However, even brief reflection on the issues posed by gene therapies or other forms of genetic engineering demonstrate that biotechnologies can also have socio-ethical and legal implications that extend beyond the strictly medical realm to concerns about public health or environmental ethics (e.g., risk of epidemics through the introduction of animal pathogens into the human population).

To be sure, nanomedicine offers many exciting new possibilities and poses numerous significant socio-ethical challenges. There will, for example, be concerns related to constraints on experimentation on human research subjects that will pose very real challenges for research ethics committees, health policy makers and regulators. As noted above, both benefits and harms may result from the introduction of nanoparticles into the human body. As is the case with all forms of technological innovation, some 'skilling-up' to learn about the basic science and applications of nanomedicine will be needed for proper/adequate oversight and associated regulatory initiatives, and there could plausibly be legal and safety considerations particular to nanomedicine. Yet, the simple fact that the technology is different does not mean that the ethical challenges raised by such research, or the principles that must govern the ethical or legal treatment of human research participants, will differ. Whether the technology in question is a gene therapy, a genetic test, a pharmaceutical, or a nano-enhanced version of one of these, its testing on human research participants will still be subject to standard review procedures to ensure their free and informed consent, safety, and so on. [49].

To begin with, following pre-clinical animal testing that demonstrated potential effectiveness, research ethics review (based on principles of safety, efficacy, informed consent, and so on) would be required before proceeding to Phase I and Phase 2 clinical trials on humans. Similarly, in commercial contexts, the marketing of nanotechnologies will raise issues familiar to those who study organisational, business, or technology ethics. Concerns may be raised here with regards to patentability, product safety, or the social responsibility of nanotech companies – concerns reminiscent of those studied in the context of the biotech and pharmaceutical industries [49]. Thus novel scientific or clinical developments do not *necessarily* bring novel ethical considerations. While there may well be challenging *applications* of ethical precepts that warrant careful ethical consideration, new developments do not in general necessitate the articulation of entirely new ethical principles.

Keeping abreast of the latest clinical developments is a professional responsibility for medical practitioners. What will the arrival of radically new nanomedicines mean for them? We conclude this section with a note to the practicing physician, whose busy clinical life may seem like it is on the verge of being swamped by yet another technological revolution. It has been noted that practicing clinicians have faced substantial obstacles in incorporating the fruits of genetic science into their practices [50]. The (apparently) imminent arrival of nanomedicine may seem like an impending catastrophic burden on the time that the average physician can allocate to continuing education. Will the coming of nanomedicine imply a vast range of new technical skills and ethical issues for the practicing physician to master? The happy answer, here, is 'no'. For the most part, nanomedicine will likely involve incremental (if sometimes striking) changes in the

way clinical medicine is currently practiced. Nanomedicine may well bring about new ways to deliver drugs, new ways to rebuild damaged tissues, and new ways to detect pathogens and toxins. But nanomedicine will *not* fundamentally change what it means to be a physician, nor will it change the fundamental principles of medical ethics.

Do We Need 'NELSI'?

In light of the above critique, we believe that the first grants handed out to researchers seeking to study NELSI (such as two US\$1 million grants from the US National Science Foundation, given to two researchers [51]) have repeated the mistakes made by many of the granting organisations that funded ELSI research. In both the biotech and the nanotech cases, granting agencies – particularly those whose primary focus is on science – failed to see the differences between research in, say, the development of nanomedicine itself, and research into the ethical *implications* of nanomedicine. In the former case, giving out a few large grants to highly capable teams may be an excellent way to produce results. In the latter case, it is not. Providing substantial dedicated funding for ethics projects about 'big science' (e.g., US ELSI or Canadian GE3LS) has clearly stimulated collaboration, built capacity, led to more diverse research related to the way the science and biotechnology are integrated into society, and revealed the problematic nature of scientific and technological institutions [43,45]. Nevertheless, we suggest that in the case of research on the socio-ethical and legal implications of nanomedicine, what is needed now is more funding to support existing (and to stimulate new) multidisciplinary and interdisciplinary collaborative networks, alongside a broad range of smaller research projects that encourage diverse and divergent perspectives and socio-ethical analyses [22]. Funding agencies ought not to place all of their analytical eggs into only a few baskets; instead, they should support a wide diversity of researchers from the bioethics community to help map actual and emerging NELSI in order that scientists, regulators and civil society can be equipped to prevent the most problematic situations, and manage appropriately the introduction of beneficial nanotech.

The rapid advance of new technologies of all kinds, and their rapid integration into clinical practice, clearly demonstrate the need for detailed social science and empirical bioethics research to investigate the particular social and technical details and contexts in which nanotechnology will develop [52]. But this does *not* imply the need for multi-million dollar research projects focusing on ethical nuances of particular technologies. To return then to Mnyusiwalla *et al.*'s call for increased research and funding of NE³LS or NELSI, if they are understood (which we believe they ought to be) as calling *not* for a repeat of 'big team' ethics research into particular technologies, but instead as calling for support of a broader multidisciplinary discussion and capacity development, then we would agree with this aspect of their proposal. We would go a step further, however, and argue for funding directed towards the development of a broad social competency to deal with the ethical implications of new technologies in general. Funding programs exclusive to one technology or discipline, such as research premised on the notion of 'genetic exceptionalism,' would not yield comprehensive approaches to technology adaptation nor win broad support. In this regard, we make the following suggestions:

1. Ethics should be an integral part of the education and mentoring of young scientists and clinicians. We here join the chorus of scholars and educators calling for the creation of a *culture of ethics* in science [53]. Exactly how to create such a culture is a difficult – and researchable – question [54]. It is also an excellent question for funding by research

councils interested in dealing effectively with the ethical implications of novel technologies of all kinds.

2. Our universities and public regulatory bodies need to do more to produce social scientists, philosophers, legal scholars, and policy-developers with a reasonable degree of understanding of science and medicine. Most of those currently engaged in examining the ELSI of biotechnologies, for example, had to learn late in life the science needed to understand the intricacies of genetic testing or stem cell research. Granting councils should therefore make resources and opportunities available for teams dedicated to developing cross-disciplinary competency, and to research projects dedicated to determining suitable curricula for producing scientifically savvy humanists and social scientists.
3. We need to do better at educating and engaging the general public on issues related to the social and ethical implications of new technologies. How to do this is of course not an easy question, and the need for dialogue should not be mistaken for a need for persuasion [55,56]. Some will inevitably argue that the public's deficit in terms of their understanding of science is so severe that our proposal implies a Herculean effort. This, we think, is a mistaken supposition. The average university undergraduate can be taught, in just minutes, *enough* about the basic science of somatic cell nuclear transfer, for example, to allow him or her to arrive at informed opinions on the various arguments offered in relation to the ethics of human cloning. If the public is to be engaged, what we should be striving for is not perfect public understanding in pursuit of total public participation, but rather *sufficient* public understanding in pursuit of *meaningful* public participation. This, too, is a researchable – and fundable – challenge [57].

Conclusion

New, paradigm-bending technologies such as nanomedicine always present choices, and there are clearly important social and ethical concerns raised by developments in nanotechnology. We must take seriously the utopian/dystopian extremes because they set out the poles of the debate, while also reflecting to some extent the concerns of the general public. Detailed ethical analysis and social scientific critique will be needed of the near-term practical applications of nanotechnology [52]. But it is our contention that, in most cases, it is the specific context or details of the technology in question that differ (genetics, pharmaceuticals, nanotech), and not the substance of the ethical implications inherent with biomedical innovation [21]. For whether the particular technology at hand is biotechnology or nanotechnology or information technology, the over-arching questions are largely the same [58]. Who will be harmed, and who will benefit? Are the gains and losses likely to be shared equitably? How will this new technology affect us as people, and as a community? Addressing these questions will help to indicate whether any policy improvisation or new regulations are called for.

We need a combination of ethically thoughtful scientists and policy-developers, scientifically savvy academics in the social sciences and humanities, and a public with sufficient scientific literacy to participate, in an informed way, in what is sure to be an on-going set of debates about the role of science and technology in our individual and collective lives. Caution – but not cynicism – is required in discussions about the hopes for and fears of nanotechnology, and this should be part of a more robust social competency for grappling with the social and ethical issues related to novel technologies of all kinds.

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