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Scientists' perception of ethical issues in nanomedicine - a case study.

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ABSTRACT

Research and development in nanomedicine has been accompanied by the consideration of ethical issues; however, little is known about how researchers working in this area perceive such issues. Extracting data from 22 semi-structured interviews with nanomedicine practitioners, this case study explores scientists' attitude towards and knowledge of ethical issues. We found that scientists reflect with ambiguity on the reputed novelty of nanomedicine and what are ethical issues and risks in their work. Respondents see no necessity for a paradigm shift in ethical considerations, but view ethical issues in nanomedicine as overlapping with those of other areas of biomedical research. Most respondents discuss ethical issues they faced in scientific work with their colleagues but expect benefit from additional information and training on ethics. Our findings can contribute to the design of new strategies - including training programs - to engage scientists in ethical discussion and stimulate their responsibility as nanomedicine practitioners.

Keywords: ethics; nanomedicine; nanotechnology; scientists' perception; risks; qualitative study; empirical research





Scientists' perception of ethical issues in nanomedicine - a case study

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Introduction

A common feature in the topical attention to nanotechnology is that ethical issues are considered alongside research and development strategies. The field has drawn ethical discourse from a wide range of academic disciplines but scientists working in nanotechnology are also encouraged to engage with issues beyond the technical dimensions of their work. This is particularly the case in 'nanomedicine', which for the purpose of this paper is defined as the application nanotechnology achieve breakthroughs in healthcare [1]. A perceived possibility that society may view the introduction of this technology with concern and scepticism is reflected in a number of policy documents asking scientists to discuss social and ethical issues of their work. For example, a European Science Foundation Report on Nanomedicine recommends "engagement

of the scientific community in regular dialogue with the general public" [2] and the European Technology Platform on Nanomedicine recommends a number of measures including "Media training of scientists, to teach them to work with the public and especially with journalists" [1].

Evidently, those who work in nanotechnology can expect to be challenged as to their 'ethics awareness'. As a nanotechnological innovation being introduced at a time of great debate around biotechnology and biomedical ethics, nanomedicine has had its share of attention in the ethics literature. Here, questions have been about health risks and benefits, privacy issues, the potential use of therapeutics for human enhancement [3] as well as social justice and access to health care [4]. In previous studies addressing how nanotechnology researchers perceive ethics, scientists have been included as one group alongside other professionals with a more indirect engagement in the field [5-7]. However, there is limited understanding regarding what scientists 'on the ground' and specifically within the nanomedicine research field consider to be ethical issues in this context and how these scientists are positioning themselves to react to such issues in their practical work. This question has to be embedded in the wider conceptualization of the role of scientists as experts and authorities. In some countries, cultures and contexts the traditional role of scientists as authority figures has come under criticism [8], and there is a prevalent challenge in integrating the consideration of scientific complexities and their governance especially in situations where scientific and ethical questions are entwined [9].





This exploratory case study has been carried out in order to inform the debate around the role of 'ethics talk' in this field of research. It aims at understanding the perception of scientists working in nanomedicine in terms of ethical issues and risks associated with their research. This also required to look at researchers' conception of novelty and innovation of nanomedicine as well as their professional identification.





Methods

Participants

Twenty-two researchers from the Instituto de Investigação e Inovação em Saúde (13S - Institute of Research and Innovation in Health, Porto, Portugal) were selected for interviews, based on their involvement in nanomedicine research. The I³S is a consortium of the Institute for Molecular and Cell Biology (IBMC; www.ibmc.up.pt), the Institute for Biomedical Engineering (INEB; www.ineb.up.pt) and Institute for Molecular Pathology (IPATIMUP; Immunology www.ipatimup.pt), gathering a total of approximately 600 researchers working in the field of health sciences. Both the consortium as such and the respective member institutes are reflective of the considerable investment and expansion in life sciences research which has characterized the academic research environment of Portugal over the last 20 years. The environment of three institutions, established, respectively, in 1989 (IPATIMUP and INEB) and 1996 (IBMC), can be described as that of a typical European life science research institution, with English as a working language and regular participation in international research projects and science networks.

The selection of researchers as "affiliated to the nanomedicine field" was based on the criteria of working in nano research projects meeting the nanomedicine definition proposed by the European Technology Platform ("The application of nanotechnology to achieve breakthroughs in healthcare") [1] and/or the use of the keyword "nano" in their curricula vitae. Researchers with "nano" in their CV always fulfilled the first criteria; thus no

researchers in nanotechnology outside medical applications were included.

group interviewee (N=22)comprised researchers aged 24-57 years (average 35) of age, of which 11 hold a Ph.D. degree, 10 were graduate students (most of them enrolled in a Ph.D. Programme in biomedical engineering) and 1 research technician. All respondents had a minimum research experience in of 3 full years of nanomedicine, with different disciplinary backgrounds, such as chemistry, physics, biology, and engineering. microbiology, medicine participants were informed of the nature of the study and volunteered to take part in the investigation.

Semi-Structured Interview Design

Themes and questions for semi-structured interviews were designed to encompass the questions listed in Table 1 (see support information). To test the interview structure, pilot interviews were carried out with scientists from other institutions, which were not included in the final sample. The 22 deep semistructured interviews were conducted by a member of our team (HSC) at the work premises of the interviewees. The interviews had a duration of 30-40 minutes and were recorded for transcription. The anonymity of interviewees was guaranteed and respondents were asked not to talk about the content of the interview with anybody until the study was completed. All interviews took place between January and March 2008. In 2008 the database of Portuguese Nanotechnology the Network (http://www.portugalnano.net/) registered researchers with a Ph.D. degree working in the field of nanotechnology, of which 57 were working in the nanomedicine area: thus the interviewees





represented around 19% of Portuguese nanomedicine researchers.

Analysis

Transcripts were analyzed using a directed content analysis approach [10, 11] using the programme QSR NVIVO (QSR International, Australia). A coding book was created in order to categorize each extract of the interviews as representative of the different discourses that structured the meaning attached to ethics and nanomedicine. A codified categorization was developed according to the content of the interviews and the objective of the research. Coding correspondences (key words that represent the central meaning of statements) were created [12, 13]. To create and to link the codes/categories to the text segments (recorded units), we opted for a mixed approach, combining а closed (defining codes/categories a priori, based on the theoretical review of the field) with an open approach (defining codes a posteriori based on the nature of the data collected (e.g. [14]). "Nanomedicine", "ethics", and "risks" are examples of categories created a priori. In order to categorize each extract of the interviews as representative of the different 'discourses' that structured the meaning attached to "risks", we created several subcategories of "risks" based on the data which were then classified according to how and in which context they were described by the interviewees, such as: "specific risk", "new risks", "environmental risks", "health risks", "risks related to nanoparticles". For example, "nanorobots" as a "risk" was integrated in the category "health risks".

The same text segments were read and analyzed by pairs of different researchers (innovation and risk:

HSC, AP; ethics and social: HSC, AO) and classified into the respective categories and subcategories. Throughout the analysis, codification, re-codification and creation of subcategories were discussed and compared to produce a final list of homogeneous codes. The analysis was based on the original Portuguese transcripts. Two members of our team (AO, AP) were responsible for translating the key words/codified segments as well as the quotes from the transcripts that support our assertions into English.

Results

The results, presented in the following paragraphs, emerge in two main areas, one having to do with professional identification and view of nanomedicine as a research discipline and one covering risks and issues of ethical nature within this research field. A detailed graphic presentation of the results can be found in Figures 1-3 in the support information.

Professional identification and view of the field In this study we used the definition of nanomedicine established by the European Platform for Nanomedicine [1] as the main criteria for the selection of the interviewees among the I³S researchers engaged in nanomedicine research. With this term as reference, we aimed to understand which definition of nanomedicine/nanotechnology respondents operate and how they characterize nanomedicine, as a way to understand to what extent they regard nanomedicine as a new/different research discipline.

To understand whether the respondents identify themselves as working in nanomedicine, they were requested to describe their professional background and briefly describe their work and were asked direct





questions such as "Would you say that you are working in nanomedicine?". As shown in Figure 1, of the 22 interviewees, 9 showed resistance to classifying their work as nanomedicine. When asked which term would better describe their work, these respondents referred to areas that included biomedicine, biomaterials, biomedical engineering, nanotechnology. neurosciences, oncobiology, regenerative medicine and tissue engineering as those with the closest correspondence with their work. Both those identifying with the field and those who did not, refer to the definition of the term nanomedicine as "problematic". Some difficulties in identifying work as nanomedicine were suggested by respondents: the fact that it is a new and unknown field; the perceived lack of agreement on a common definition

"Some argue that its only nano if the size is below 100 nanometers and others that it may be more than 100" (Interviewee 5)

and the fact that the term was perceived to be a "buzzword". Some respondents suggested nanomedicine to be "more a type of technology than a specific scientific field" (Interviewee 18). The consideration most frequently associated with nanomedicine was "scale" and "size".

Of the 13 that identified themselves as researchers in nanomedicine, 12 described their research in nanomedicine as focused "in terms of biomaterial development" and as being "very interdisciplinary", "outside the traditional" [boundaries/categories].

Nonetheless, 17 respondents refer to nanomedicine as a "new area". Only one interviewee stated that the area was not new. The predominant argument

advanced for true novelty was related to size and scale, but some interviewees also referred to novelty through technological options, implications and paradigms.

Some interviewees – exclusively more senior researchers – described the field more ambiguously. On the one hand they considered the area new because it corresponds to an evolution of knowledge (implications, technique, paradigm) and in terms of working at the nanometer scale, while at the same time these respondents reflected that the area was not entirely "new" because some research under this label is not.

"The word nanomedicine as a term, just as tissue engineering, for example, and many others, is a bit in fashion. Almost everything came to be included in this concept. A few years ago it was not common to use the terminology nanomedicine, it wasn't in fashion, but already then there were scientists working in nanomedicine" (Interviewee 15)

Indeed, when asked whether they considered nanomedicine "a buzzword", a "show-off" term, more than half of the respondents agreed that it was often used in this way not only in media but also by scientists. Nevertheless, respondents felt that the current attention of funding agencies to nanotechnology is justified.

Concepts of risks and ethics

As presented in Figure 2, of the 22 scientists interviewed, 17 identified risks in nanomedicine. The possible toxic effect of nanoparticles on human health was identified by the majority (14/17), but only





a small minority considered these risks to be specific for nanomedicine. All respondents who identified risks stated that they do not give more relevance to the risks of nanomedicine than they do for other areas of biomedical research. Other risks associated with environmental impact (6/17) and nanorobots (2/17) and "ethical risks" (term used by one respondent when asked about potential risks in nanomedicine) (1/17) were also mentioned, but the majority of respondents argued that any novel technology involves risk. Regarding the risks associated with the toxicity of nanoparticles - in particular the cumulative effects of the nanoparticles on human health, as referred to by 14 respondents -10 of the interviewees believe that a risk evaluation will and/or should be carried out to guarantee that products and therapeutic agents carrying nanostructures are safe to use, before these products are marketed, in the same way as is already happening with pharmacological drugs and conventional therapies.

When confronted with the questions "Are you able to identify any ethical question in nanomedicine?" and "What is an ethical question for you?", the theme of risk resurfaces as inexorably entwined with ethics.

"For example, the use of nanoparticles is a question that I - I don't work with nanoparticles – acknowledge that one has to analyze in terms of the risk and for which the risks were also associated with ethics. One doesn't use a drug that causes harm. Before being safe to use, there has to be a series of studies, as for any drug. In the case of nanoparticles, as they are small, they can migrate, accumulate in particular organs and we don't know what will happen, whether the accumulation of these particles

will have secondary effects that are even worse than the ones the person had. Evidently, this has to be analyzed" (Interviewee 15)

"Imagine that all [nanoparticles, nanomaterials] are toxic – the ethical question has to do with predicting the consequences" (Interviewee 21)

"I can not recommend that a material, developed in a laboratory and which has an extraordinary effect on bone regeneration, is used if one does not know which consequences it may have on other tissues (...). If I do not do studies I am violating ethical principles that should be imposed on the scientific activity." (Interviewee 20)

As depicted in Figure 3, of the 22 subjects, only 6 identified ethical questions in nanomedicine: 3 referred to the toxicity of nanoparticles and 3 to the use of embryonic stem cells in human therapeutics. Several respondents underline that the ethical questions appearing in nanomedicine are not different from ethical questions in other fields of biomedical research.

"I believe they [ethical questions in nanomedicine] won't be very different from those existing presently. Without being termed "nanomedicine", treatments with living cells or with the cells from a patient are already made, or tests of new biological therapies are being made in persons with cancer...and in these treatments there are ethical questions, obviously. Will it really work? Which groups should benefit from these treatments? These questions are the same for nanomedicine (...). As this is a very wide area, including various potential applications (some with great social impact) there is always





ethical concern (...). Ethical questions in nanomedicine are given much relevance but they aren't very different from those existing in other areas: biology, biomedicine, pharmacology" (Interviewee 11)

To follow up what concept of 'ethics' respondents were operating and reflecting against, we questioned the interviewees about what they consider to be "an ethical question" and asked them to give concrete examples of situations confronting them with ethical questions.

Half of the respondents' answers could be coded to affiliating ethics as "taking responsibility for ones actions". When asked about potential ethical questions in general scientific research, nearly all (21/22) respondents were able to identify such questions. Of this group, 14 gave in vivo research on animals as an example of such an ethical question. Other ethical questions identified include the use of embryonic stem cells (5), research with human subjects (5), misuse of funds (5), environmental protection (2), occupational health and safety issues for scientific personnel (2), ethical questions in clinical practice (5) and 'norms' for conduct in scientific research including transparency and use of funds (2). Seven of the interviewees associated the question of ethics to a situation that evokes disagreement and polemics, about how to act and which principles and rules not to violate.

Although all (21) interviewees were able to identify and define an "ethical issue", only half of the respondents confirmed to have been personally confronted with an ethical question in their scientific work. Animal experimentation, clinical practice, misuse of funds and informed consent were named but only 2 identified these problems as related specifically to their current work in nanomedicine.

In resolving ethical issues in their scientific work including actually resolving ethical issues that they have encountered as well as how they would hypothetically resolve these issues would they encounter them - the main resources for our respondents are discussions with other colleagues. Many respondents indicated that they discuss, share doubts and opinions and try to clarify issues as far as possible with colleagues. These colleagues may be from the own research group, from the own institution or from other national and international institutions, and some of the interviewees also mention seeking the advice of colleagues they consider "opinion leaders" in specific areas:

"I look for the opinion of colleagues who face the same or similar problems in their own countries, who know or at least have an opinion, and I try to find out how they have acted" (Interviewee 10)

Of the 22, 19 referred to first turning to colleagues, and 3 considered an ethics committee the first instance of advice. Among the 19 considering colleagues to be the primary resource, reference is also made to ethics committees (4), literature (5), legislation (2) and the internet (2) as possible sources of guidance.

Six respondents spontaneously indicated that they have had training in ethics during their post-graduate education in biomedical engineering – although underlining that this training was more oriented towards the questions of informed consent. When asked about whether they were interested in further





training in ethics and ethical debate, fast all interviewees (20/22) stated that they would benefit from this, but several (8/22) underlined that for such a training to be relevant for them, it should focus on the ethical issues of relevance for their work in nanomedicine. Some respondents however, stressed the need for third-party assessment from outside:

"What I gained [from external ethical advice] was having the notion that there is a great need in research to always have an ethic committee to make evaluations. There shouldn't be research without always having someone from ethics or at least someone with an ethical conscience associated to it. Because we are focused on the research and sometimes we lose the overall view. Nobody is perfect... research often does wrong in its narrow focus, we live 'quote-unquote' obsessed by a particular theme, an area, and sometimes we lose the notion of the overall view. It's really necessary to have somebody from the outside, with a more global and broad view who opens up the discussion." (Interviewee 4)

Discussion

By providing data from in-depth interviews with researchers engaged in the field of nanomedicine, this case-study report adds empirical information to the often speculative discussion around ethical issues on this topic. While it has been suggested that nanomedical ethics as a field has not received much attention [15] it certainly cannot be alleged that the topic has not been charted analytically (e.g. [3-5, 16-18]). In addition to these mainly theoretical discussions of potential ethical issues, the general

public perception has been mapped through public consultations (e. g. [19]). However, what is missing is layered empirical data on how practitioners are conceptualising and interacting with the ethical aspects of nanomedicine research.

In some other nanotechnology contexts, scientists are often interviewed alongside other professionals. Ebbeling [5] included interviews with financiers and science journalists. Rogers-Hayden and Pidgeon interviewed 20 'stakeholders' from civil society groups, science and technology studies and science communication fields [6]. Petersen and Anderson interviewed twenty individuals active nanotechnology research, but with a majority of 'downstream' scientists (toxicologists, epidemiologists, and other public health scientists) who study and monitor the environmental materials that are created by the 'upstream' scientists [7]. The different attitudes to risk of these groups have been observed elsewhere, e.g. in an interview project with 20 (12 'upstream' and 8 'downstream') US nanotechnology scientists [20]. Other scholars have analysed the positions of prominent nanotechnology exponents [21] but less attention has been paid to scientists performing the actual research in nanomedicine.

The paradigm study in quantitative analysis in the area was conducted by McGinn [22] who probed the attitudes about ethics in relation to nanotechnology of over a thousand nanotechnology scientists from 13 US university research facilities. Generally, the range and distribution of views on ethics in relation to nanomedicine reflected in our qualitative data are close to those reflected in the McGinn nanotechnology study. While the presented research





is qualitative without aiming to make statistically generalisable predictions, it includes a significant representation of nanomedicine researchers in Portugal. It covers all nanomedicine researchers associated with an institution - *Instituto de Investigação* e *Inovação* em Saúde (I³S) - recognized as a national and international reference in this field.

A great majority of respondents agreed that ethical responsibilities of nanotechnology researchers go beyond simply following rules and that there should be clear ethical guidelines for the responsible conduct of nanotechnology research. Similarly, the scientists in our interviews generally recognize gaps in their own knowledge of ethical issues but they are not ignorant of such issues, nor do they deny that ethical questions have importance and that scientists have a responsibility in addressing them. If anything, these findings are in contrast to interviews with European nanotechnologists conducted by Wienroth [23] who finds that his respondents consider "ethics an issue for other actors to consider" and who dismiss challenges such as feasibility and risk as problems to be solved at a later stage. This is not reflected in the view of most of our respondents who are interested precisely in questions of feasibility and risk.

We do find, however, that our respondents have less inclination to engage with questions that are perceived as entirely remote. The scientists are aware of general and mediatic discussions that evolve around nanotechnology as hugely beneficial or a potentially catastrophic impact on humankind, but do not identify a link between these extreme scenarios and their own work. Even within

nanomedicine, respondents make limited concrete links to technology that is projected to arise out of that context - such as the nanotechnological encapsulation of compounds to facilitate better drug delivery, improved treatments for neurodegenerative diseases, improved surgical robotic tools [24], medical imaging [25, 26], and many other applications that have been forecasted as groundbreaking developments in nanomedicine [27, 28] unless their own research is directly related to it.

When prompted, respondents are able to exercise what ethical issues these technologies may involve, but there is a distinct sense that respondents feel unqualified to stray into territory where they do not consider themselves to have sufficient expertise. While this reluctance could be considered as an abjuration of moral responsibility, maybe the more justified interpretation is that scientists are trained not to rush to judgement in 'unfamiliar' fields. In accordance with the McGinn study, the great majority of respondents showed curiosity about ethics and was willing to undergo training in ethical issues. McGinn suggests a correlation "between past respondent exposure to ethics-education courses and strength of respondent belief that study of ethical issues related to science and engineering should become a standard part of the education of future engineers and scientists" [22] - indeed at least six of our respondents had participated in mandatory ethics training.

From the perspective of scientists involved in nanomedicine, ethical themes can be classified as either belonging to an 'inner sphere' where their work is under ethical scrutiny; or, secondly, an 'outer sphere' where questions are raised about the





philosophical social implications and of nanotechnology in the abstract. There is, of course, much practical and conceptual overlap between these spheres - most evidently when transitioning discourse from the 'inner' sphere of nano-science to the 'outer sphere' of technological diffusion in society. Similarly McGinn [29] distinguishes between the micro-social, the meso-social and the macro-social spheres and other authors have suggested comparable distinctions. [30, 31]. There is a pronounced tendency among our respondents to focus on 'inner sphere' ethics - but not exclusively.

The finding that many of our respondents engage little with the issues arising from potential application of their research may seem at odds with McGinn's finding that scientists are ready to alert appropriate authorities if there is reason to believe that their work will be applied in a manner that may pose a risk of significant harm to human beings. However, while this represents answers to a direct question in McGinn's study, our respondents were not prompted directly to consider the technology implications of their research. The fact that about half of our respondents refer to the necessity of safety evaluations indicates that they are indeed concerned with potential harmful effects of technology applications.

Our results are consistent with one of the main conclusions of a recent article [32] that examines ethical issues in the literature referring to nanomedicine and asks whether these issues are new and unique. Much of the normative reflection and socio-ethical debate continues to concentrate on key issues that relate to the risks *and* great promises of clinical biomedical applications of nanotechnology,

such as human enhancement and safety, informed patient's rights and clinical Regardless of differing opinions, the review concludes that none of this ethical issues associated with nanomedicine are new or unique. In the present exploratory case study, the respondents did not identify any scientific development that may give raise to unique, novel or particularly severe ethical problem - rather they suggested that problems appearing in nanomedicine existed and were equally relevant in other fields of biomedical research. This question has generated some evolved discussion among ethicists - some justifying the deluge of research and discussion that has focused on the ethics of nanotechnology with its unique and/or paradigm-changing nature whereas others merely find nanotechnology a useful case study in the wider ethical discourse on 'science & society'. Critics have pointed out that too much time is devoted to speculative science fiction and others try to make sense of the fact that unprecedented scores of ethics analysts have 'descended' on the field in recent years [31, 33-36]. This leads to a somewhat precarious position for scientists who are, as we have seen, overall open to engage in and receptive to ethics guidance and training, but remain largely unaware that the type of discourse and guidance is itself a politically and academically controversial topic. On the other hand, greater involvement of nanomedicine researchers is likely to help focusing the ethics debate on the type of applications that are under scientific and technological consideration, and prevent it from spending efforts on analysing science fiction scenarios. Considering the willingness of scientists to participate, we think there is scope for more interdisciplinary research and dissemination activities, which in turn could be an efficient way to





ensure that on the one hand the ethics discourse takes nanomedicine research into account and that on the other hand nanomedical research implements a continuous ethical discourse.

Conclusion

From the analysis of 22 in-depth semi-structured interviews - with a group of researchers with different disciplinary backgrounds working in the field of nanomedicine - we concluded that scientists generally had a positive attitude towards ethics and were willing to engage more with the topic, provided this was done in a context relevant to their research. They are aware that they can make an important contribution to the public discourse. Given the privileged role of scientists as a respected and trusted group of professionals, their perception of ethical issues is important. In particular, the motivation these scientists show in engaging with ethical issues could be harnessed in training programs directed to researchers and graduate students. Overall, this would help scientists to act proactively on the ethical issues discussed in the application of nanotechnology in healthcare and increase capacity for reflection and awareness of ethical issues in their practical work. This first indepth qualitative study of ethics from the point of view of nanomedicine researchers provides a relevant empirical foundation and framework for future Europe-wide studies in nanomedical ethics aiming to inform the common research agenda and explicit training programmes for scientists and graduate students (in this field).

Future perspective

developments The of nanotechnology engineering at the nanoscale as well as the application in health constitute an ongoing challenge for society. This is true today and will not change soon as the field is fast moving. While the current state of the structural ethical issues posed by nanomedicine may not be so different from other biomedical fields, this may change in the future. National and European public investment in nanoscience and nanotechnology continues to increase for medical devices and nanotechnology based medicines. "From the lab to the clinic" becomes the slogan that will mark the next step to ensure that more and more medical products based on this technology will arrive on the market. The expected success of these diagnostics and therapeutics innovations will raise new concerns about safe product implementation, regulatory policies and economical governance and also possibly raise socio-ethical issues that need to be discussed publicly. We hold that it is of utmost importance that scientists working in the field become more engaged in ethics in order to be prepared to identify and assess new or additional issues (and possible responses to these issues). Providing an "expert assessment" of some presumed trends and expectations on how the field will evolve, will have an influence on the debates of other audiences (academic, regulatory, and industry stakeholders). The contribution of scientists analyzing and evaluating ethical issues can help to minimize the gap between "fantasy" and "reality" and will increase the awareness of the advantages of nanomedicine to improve human health and its risks. Obviously this does not mean that scientists should





"dominate" the ethical discussion, but the debate should be more inclusive. There is actually a lack of reliable empirical data on how practitioners are perceiving and conceptualizing the current state of "ethical issues of nanomedicine research". In this context, what we want to emphasize is the need to incorporate expert analysis (scientists working in basic and applied nanomedical research) to inform the normative reflection and to counter speculative views on nanoethics. Building on the results of this exploratory case study, we envisage cross-cultural empirical research involving other countries and the respective actors and institutions. We believe that the views of scientists constitute a significant contribution to the public discussion of relevant ethical issues regarding nanotechnology applications over the next 5-10 years.

Executive summary

- Most of the scientists interviewed identified ethical issues in general research and explicated risks with nanomedicine, but only less than a half identified ethical issues in nanomedicine and most recognized not to be familiar with the majority of the "nanomedicine ethical issues", as described in literature, such as human enhancement using implantable nanodevices.
- Scientists reflect with ambiguity on the reputed novelty of an emerging 'nanomedicine' field and what constitutes an ethical issue and/or a risk in their work. Whereas some technical innovations are seen as novel, they see no necessity for a paradigm shift in ethical considerations.
- No new ethical problems specific for nanomedicine were identified; rather the

- respondents viewed ethical issues in nanomedicine as overlapping with those of other areas of biomedical research.
- The majority of scientists identified discussion with colleagues as their main resource for dealing with ethical issues they faced in scientific work.
- The scientists interviewed consider that they
 would benefit from additional information
 and involvement of the social
 sciences/humanities in their work and would
 be motivated to participate in ethics training
 given that this is focused on issues relevant
 for their work in nanomedicine.
- Scientists' involvement in the ethical discussion related to the application of nanotechnology in healthcare should be encouraged. This is particularly likely to be successful considering scientists' motivation to engage in activities specifically targeting ethics in nanomedicine.

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Ethical conduct of research

All interviewees were informed and volunteered to participate in the study and their identities were kept confidential. All figures and tables included in this manuscript are original.



Bibliography

- European Commission European
 Technology Platform on Nanomedicine:
 Nanotechnology for Health Strategic Research
 Agenda, Brussels (2006).
- European Science Foundation:
 Nanomedicine: An ESF European Medical
 Research Councils (EMRC) Forward Look Report,
 European Science Foundation, Strasbourg (2005).
- 3. Bawa R, Johnson S: The ethical dimensions of nanomedicine. *Medical Clinics of North America* 91, 881-887 (2007).
- 4. Resnik DB, Tinkle SS: Ethics in nanomedicine. *Nanomedicine* 2, 345-350 (2007).
- 5. Ebeling MFE: Mediating uncertainty Communicating the financial risks of nanotechnologies. *Science Communication* 29, 335-361 (2008).
- 6. Rogers-Hayden T, Pidgeon N: Moving engagement "upstream"? Nanotechnologies and the Royal Society and Royal Academy of Engineering's inquiry. *Public Understanding of Science* 16, 345-364 (2007).
- 7. Petersen A, Anderson A: A question of balance or blind faith?: scientists' and policymakers' representations of the benefits and risks of nanotechnologies. *NanoEthics* 1, 243-256 (2007).
- 8. Martin B, Richards E: Scientific knowledge, controversy, and public decision-making. In: Handbook of Science and Technology Studies, Jasanoff S, Markle GE, Petersen JC, Pinch T (Eds.). Sage, Newbury Park, 506-526 (1995).
- 9. Sturgis P, Allum N: Science in society: reevaluating the deficit model of public attitudes. *Public Understanding of Science* 13, 55-74 (2004).

- 10. Hsieh HF, Shannon SE: Three approaches to qualitative content analysis. *Qualitative Health Research* 15, 1277-1288 (2005).
- 11. Patton MQ: Qualitative Research and Evaluation Methods. SAGE Publications, Thousand Oaks (2002).
- 12. Vala J: *A análise de conteúdo*. In: *Metodologia das Ciências Sociais*, Silva AS, Pinto JM (Eds.). Afrontamento, Porto (1986).
- 13. Krippendorff K: Content Analysis: An Introduction to Its Methodology (2nd). SAGE Publications, Thousand Oaks (2004).
- Ghiglione R, Matalon B: Les Enquêtes
 Sociologiques: Théories et Pratiques. Armand Colin,
 Paris (1998).
- 15. Allhoff F: The coming era of nanomedicine. *American Journal of Bioethics* 9, 3-11 (2009).
- 16. Bawa R, Johnson S: Emerging issues in nanomedicine and ethics In: Nanotechnology and society: Current and emerging ethical issues, Allhoff F, Lin P (Eds.). Springer Netherlands, 207-223 (2008).
- 17. Sandler R: Nanomedicine and nanomedical ethics. *American Journal of Bioethics* 9, 16-17 (2009).
- 18. Ebbesen M, Jensen TG: Nanomedicine: Techniques, potentials, and ethical implications. *Journal of Biomedicine and Biotechnology* 2006, 51516 (2006).
- 19. Hart Research Associates Inc.: Awareness of and Attitudes Toward Nanotechnology and Synthetic Biology: A Report of Findings Based on a National Survey Among Adults. Conducted on Behalf of the Project on Emerging Nanotechnologies., The Woodrow Wilson International Center for Scholars (2008); available at:





- http://www.nanotechproject.org/process/assets/files/8286/nano_synbio.pdf Accessed 26 Jul, 2010.
- 20. Powell M: New risk or old risk, high risk or no risk? How scientists' standpoints shape their nanotechnology risk frames. *Health, Risk and Society* 9, 173 190 (2007).
- 21. Bueno O: The Drexler-Smalley debate on nanotechnology: Incommensurability at work? In: Nanotechnology Challenges: Implications for Philosophy, Ethics and Society, Schummer J, Baird D (Eds.). World Scientific Publishing, 29-48 (2004).
- 22. McGinn R: Ethics and nanotechnology: Views of nanotechnology researchers. *NanoEthics* 2, 101-131 (2008).
- 23. Wienroth M: Disciplinarity and research identity in nanoscale science and technologies. In: Size Matters. Nanobiotechnology and Nano-Medicine: Ethical, Legal and Social Aspects, Ach JS, Weidemann C (Eds.). Lit, Münster, 157-177 (2009).
- 24. Leary SP, Liu CY, Apuzzo MLI: Toward the emergence of nanoneurosurgery: Part III Nanomedicine: Targeted nanotherapy, nanosurgery, and progress toward the realization of nanoneurosurgery. *Neurosurgery* 58, 1009-1025 (2006).
- 25. Sullivan DC, Ferrari M: Nanotechnology and tumor imaging: seizing an opportunity. *Molecular Imaging* 3, 364-369 (2004).
- 26. Pilarski LM, Mehta MD, Caulfield T, Kaler KVIS, Backhouse CF: *Microsystems and nanoscience for biomedical applications: A view to the future.* In: *Nanotechnology: Risk, Ethics and Law,* Hunt G, Mehta M (Eds.). Earthscan, London, 35-42 (2006).
- 27. Wagner V, Dullaart A, Bock AK, Zweck A: The emerging nanomedicine landscape. *Nature Biotechnology* 24, 1211-1217 (2006).

- 28. Sheremeta L: Nanotechnologies and the ethical conduct of research involving human subjects. In: Nanotechnology: Risk, Ethics and Law, Hunt G, Mehta M (Eds.). Earthscan, London, 247-258 (2006).
- 29. McGinn R: Nanotechnology and Ethics: A Short Guide to Ethical Responsibilities of Nanotechnology Researchers at NNIN Laboratories, National Nanotechnology Infrastructure Network (2008); available at: http://sei.nnin.org/doc/NANOTECHNOLOGY_AND_E THICS_GUIDE.pdf Accessed 26 Jul 2010.
- 30. Foladori G, Invernizzi N, Záyago E: Two dimensions of the ethical problems related to nanotechnology. *NanoEthics* 3, 121-127 (2009).
- 31. Godman M: But is it unique to nanotechnology? *Science and Engineering Ethics* 14, 391-403 (2008).
- 32. Kuiken T: Nanomedicine and ethics: is there anything new or unique? *Wiley Interdisciplinary Reviews: Nanomedicine and Nanobiotechnology* Published online at 20 Apr 2010, (2010).
- 33. Wood S, Geldart A, Jones R: Crystallizing the nanotechnology debate. *Technology Analysis & Strategic Management* 20, 13-27 (2008).
- 34. Nordmann A: If and then: A critique of speculative nanoethics. *NanoEthics* 1, 31-46 (2007).
- 35. Grunwald A: Nanotechnology A new field of ethical inquiry? *Science and Engineering Ethics* 11, 187-201 (2005).
- 36. Grunwald A: From speculative nanoethics to explorative philosophy of nanotechnology. *NanoEthics* Published online at 25 May 2010, (2010).





Figure 1 – Nanomedicine and Science Innovation categories. The figure between brackets correspond to the number of answers. * According to the definition of the European Platform for Nanomedicine.

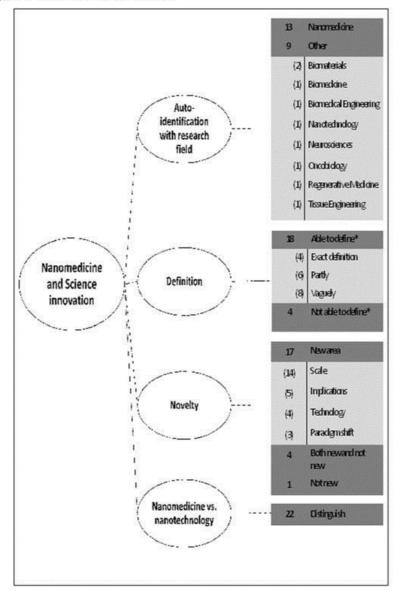




Figure 2 – Nanomedicine and risk categories. The figure between brackets correspond to the number of answers.

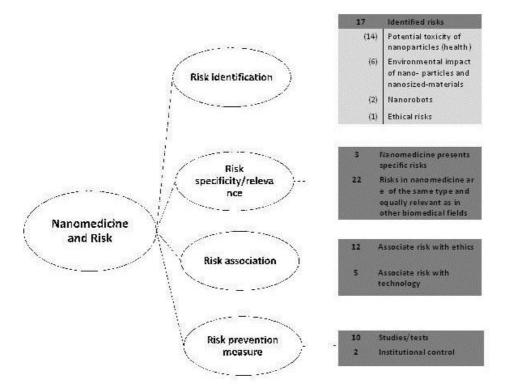




Figure 3 – Nanomedicine and ethics categories. The figure between brackets correspond to the number of answers.

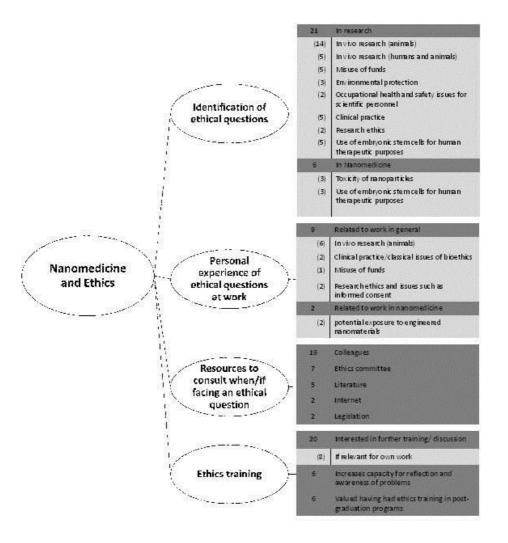




Table 1 Thematic interview structure

In addition to running aim-related questions, respondents were asked some questions for reference, including:

Position — (degree? experience? background?)
Motivation
(describe your project)
(describe your work)
(Would you say that you are working in nanotechnology?)
(Would you say that you are working in nanomedicine?)

A. Characterising the field

A1 Which definition of nanomedicine do respondents operate?

A2 Are respondents of the opinion that nanotechnology/nanomedicine is used as an 'empty label'?

IF Yes

A2.(a). why is it empty? (tradition, scope, buzz...) A2.(b). who uses it in this way? (themselves, colleagues, media...)

A2.(c). why? (to get funding, to gain recognition...)
A3 Do respondents feel that the current attention of funding agencies to nanotechnology is justified?
A4 Do respondents think that nanotechnology brings a paradigm shift in

(a) their own field (b) in other fields (c) in general A5 Do respondents think that nanotechnology has the potential to trigger such a paradigm shift? IF yes

(a) in what area, (b) in what way, (c) with what consequences (d) how soon?

A. Risks

A6 Do respondents think that nanomedicine harbours risks? IF yes

- (a) what type of risk?
- (b) how novel are these risks?
- (c) are these increased risks in comparison with other technologies? (what comparison)

A7 Do respondents think that nanomedicine/nanotechnology is particularly interdisciplinary? IF yes

A7.(a). what kind of experiences do respondents describe?
A7.(b). what kind of challenges do respondents describe?

B. Ethics, stance

B1 What is "ethics" to a respondent?

B2 Do respondents reflect on the ethical implications of their own work?

B3 How informed are respondents about 'ethical issues' in relation to nanomedicine

B4 Have respondents ever encountered a situation where they felt they needed to engage in ethical considerations/ deal with ethical problems?

C. Ethics, communication

C1 What background do respondents draw on when discussing ethics?

- C2 Do respondents communicate about ethical issues with their colleagues? C3 What resources to respondents turn to for ethical decision making?
- C4 Do respondents feel they would benefit from "ethics training"?
- C5 In what way do respondents feel that they benefit from the involvement of the social sciences/ philosophy in their work?





