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J Med Ethics 2010 36: 409-414
doi: 10.1136/jme.2009.031674

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Received 12 June 2009
Revised 7 December 2009
Accepted 8 December 2009

ABSTRACT

The deliberative ethics guidelines elaborated and implemented by members of the IFOM-IEO Campus (Firc Institute of Molecular Oncology (IFOM) and the European Institute of Oncology (IEO)). These should serve the dual purpose of establishing a minimal set of standard rules for bioethical debate and any ensuing decision-making process, especially for the perspective of providing real instruments to foster public engagement and public awareness on the ethical issues involved in biomedical research. It is shown that these guidelines instantiate the scheme of one of the correct ways of debating formalised by the western thought.

A PLEA FOR DELIBERATIVE ETHICS

The 20th century was the century of physics. The 21st century has instead been predicted to be that of biomedicine. In less than a decade, this prophecy appears to be well on its way to being fulfilled. Perhaps not surprisingly, the technical, theoretical and applicative progress of the biomedical sciences is changing the cultural landscape, even before their real benefits are felt by society. As in every transition phase, we are, therefore, in a peculiar predicament: on the one hand, progress holds great promises; on the other, it generates apprehension, partly because of the speed at which this progress is being achieved. Societal paradigm shifts are necessarily slower than scientific ones, and the raging debates on issues such as stem cell research, genetic profiling, genetically modified organisms, synthetic life and definitions of life and death are just a few examples of how society at large is being challenged with changes and issues that were unthinkable even a decade ago. The fact that these changes directly touch our very essence, as individual human beings, adds an additional element of wariness to the love–hate relationship between science and society. As a consequence, bioethics is playing an ever-increasing role and becoming more and more pervasive within society. Ethical committees and ethical codes proliferate at every level: institutional, national, supranational (eg, the European Union) and even global. Indeed, virtually all biomedical research programmes that are financially supported by a national or supranational organisation can proceed only with the approval of at least one ethical committee. Additionally, virtually all biomedical research institutions have a local ethical code and refer to a local ethical committee.

This is not the right forum to discuss whether we genuinely benefit from this abundance of ethical codes and ethical committees. Undoubtedly, there are advantages related to the regulation of the ethical sustainability of biomedical research. We run the risk, however, that in the absence of a shared methodology to elaborate ethical codes and/or to guide the work of ethical committees, these might fall prey to partisan agendas (or become paralysed by clashes between partisan agendas), thus reducing the ethical review process to a mere ethical gendarmerie and diverting it from its true mission, that of being the ethical companion to biomedical research.

An even more relevant issue is the growing request for public engagement in decision making that concerns biosciences. This idea is widely acknowledged but has, so far, received only considerable lip service. The realities of public engagement have been difficult to address. We harbour serious reservations as to whether any existing ethical committee or ethical code really enhances societal participation in the bioethical debate, public ethical awareness or societal impact on the decision-making process. In reality, the public has little recourse but to trust the capacity of ethical committees to do their work and to rely on the statements contained in ethical codes. We feel that this present state of affairs is unsatisfactory.

We feel that this present state of affairs is unsatisfactory. On account of these issues, members of the IFOM-IEO Campus (Firc Institute of Molecular Oncology (IFOM) and the European Institute of Oncology (IEO)) (see box 1) have proposed and instantiated something different: a set of deliberative ethics guidelines (hereinafter DEGs, see Appendix, also published at http://www.ifom-ieo-campus.it). These, as we will illustrate, serve the dual purpose of establishing a minimal set of standard rules for bioethical debate and any ensuing decision-making process and providing real instruments to foster public engagement and public awareness on the ethical issues involved in biomedical research.

A GLIMPSE INTO DELIBERATION

The operative word in the DEGs is *deliberative*. What exactly do we mean by this term? *Deliberation* is the process by which a community or a group of individuals tries to reach a common decision starting from different positions through a frank debate based on rational arguments and counterarguments. Its origins can be traced to the dawn of Western culture, when democracy first laid its roots—for example, in Athens and in Syracuse,[1–4] or when politics became an issue for philosophical analysis, as was the case for Plato and Aristotle. This idea of deliberation, however, has permeated throughout the history of Western political philosophy, albeit sometimes as an

Box 1 The research institution

The IFOM-IEO Campus (Firc Institute of Molecular Oncology (IFOM) and the European Institute of Oncology (IEO)) (http://www.ifom-ieo-campus.it) is one of largest European centres devoted to research on the molecular bases of cancer and related topics. It hosts around 600 young and senior scientists from 38 research groups that are supported by 11 technological units. The Campus was founded through the joint efforts of two institutions: the IEO, a comprehensive cancer centre, and the IFOM, a non-profit research centre dedicated to the study of tumour formation and development that is backed by the Italian Foundation for Cancer Research. The Campus also hosts the SEMM (http://www.semm.it), which was founded jointly by IFOM and IEO together with other institutions and which is devoted to higher education through three PhD programs: Molecular Medicine, Medical Nanotechnologies and Foundations of the Life Sciences and Their Ethical Consequences.

underground river, from the Middle Ages through the Age of Humanism, the Renaissance and the modern era. It has now been rediscovered by many American authors in the form of the so-called *deliberative democracy*.[5–12]

Briefly explained, deliberative democracy is a form of direct democracy that allows citizens to participate actively in the decision-making process through a strongly rational debate in which individual positions are criticised and supported by means of well-crafted arguments. The core of deliberative democracy, therefore, consists in proposing a blueprint for reaching political decisions based on a rational discussion in which all participants tackle the problem under discussion, propose solutions and argue for and against them until, hopefully, one of the solutions is considered to be the best one based on its support by the most solid arguments and because it has successfully stood up to criticism.

The analysis of the strengths and the weaknesses of this form of direct democracy are beyond the scope of this discussion. However, it takes a short leap of the imagination to realise that such a blueprint can be applied to the case of moral decision making and a fortiori to the case of bioethical decision making. Indeed, this is exactly the framework of the DEGs. In this context, we note that there are a number of bioethical papers that include the term *deliberation* in their title or whose content concerns applications or examples of deliberation in the bioethical field.[13–16] Unfortunately, neither deliberative democracy theorists nor advocates of deliberative bioethics invest much time in discussing how deliberation should actually be accomplished and implemented. It would appear that we all know how to accomplish the deliberative process, but in all truth, very few of us are really acquainted with its epistemological, methodological and argumentative structures.

This is precisely why members of the IFOM-IEO Campus, who strongly support the idea of deliberative bioethics, have decided to elaborate and implement the DEGs. These are precisely tailored to the epistemological, methodological and argumentative structures of the deliberative process for decision making in the field of biomedicine. Two unwavering principles underlie the DEGs. First, deliberation forms the basis of Western thinking. Thus, it is not simply an appropriate path for bioethical decision making, but it could actually be the only practicable one. Second, contemporary science is a process that is strongly based on deliberative argumentation. Thus, scientists are qualified to mould the structure of a deliberative blueprint for ethical decision making (although, clearly, they hold no particularly privileged position when it comes to deciding upon the content of the debate or its outcome).

WHY CAN DEGS COME FROM SCIENTISTS?

As just mentioned, scientists are perhaps legitimated in proposing guidelines for ethical deliberations. However, what are their motivations for doing so? Furthermore, is there a correct way to achieve this? Members of the IFOM-IEO Campus have presented the DEGs as a group of individuals rather than as an institution. The major reason for this choice is that an ethical deliberation involves individuals who agree to convene to discuss a moral conflict and aim to find common solution. To set the right tone, these scientists felt that they should represent themselves as individuals, perhaps depositary of distinctively valuable knowledge but individuals nevertheless. By doing this, they acknowledged, as responsible individuals and scientists, their non-neutrality vis-à-vis the ethical consequences of their scientific endeavours. The term *non-neutrality* is intended in the sense of the values that scientists refer to rather than in the sense that science is value laden (under this position, the well-known Weberian distinction between *Wertfreiheit* and *Wertbeziehung* lies).[17 18] There are, of course, very good reasons for such non-neutrality. For example, research is largely supported by the public, be it through national governments or non-profit organisations, including charities, whose impact on the funding landscape is increasing, especially within Europe. The ethical covenant between science and society must, therefore, be based on a receive-and-give-back attitude. The major deliverables expected from science are, of course, knowledge, and hence culture, and practical applications. However, the framework in which these products are delivered is important. In a non-neutral framework, the scientists of the IFOM-IEO Campus believe that one possible way of giving back is to stimulate society into entering a serious debate on the ethical implications of the biomedical results. However, a high-quality public debate on the ethical sustainability of biomedical research is more easily said than done. It is with this aim in mind that these scientists have elaborated and proposed guidelines that can encourage future methodological discussions. If they are successful, they will have made an important step forward in promoting the progress of an informed ethical debate in biomedicine.

We live in an age in which new biomedical results and techniques are proposed on an almost daily basis; most of these have serious ethical implications. The media is rife with debates and commentaries on the ethical sustainability, that is, on the possible ethical justifiability, of such innovations, but the discussions are, unfortunately, frequently poor and superficial. Often, no arguments are presented for or against the production and/or use of new biological entities, processes or techniques; slogans and sound bites are offered instead, frequently vitiated by ideological or dogmatic prejudices. Needless to say, moral prejudices have no place within a sound ethical position, which instead must be supported by good reasons, that is, by robust arguments.

Undoubtedly, ethics is not just a question of arguments alone; that would reduce it to mere sophistry. However, ethics cannot exist without arguments. Of course, we are not concerned here with that part of ethics that deals with ethics itself, that is, with meta-ethics, nor are we speaking about the analytical tradition of ethics, where arguments are more important than moral content. Instead, this paper addresses the application of ethics to the biomedical field. There are real bioethical issues with real and urgent moral conflicts that must be resolved to safeguard, on the

one hand, the continuation of indispensable biomedical research and, on the other, its ethical sustainability. To attain these goals, the engagement of the general public will not be sufficient. Rather we need the engagement of a public that knows how to discuss and propose arguments for a position it deems is morally acceptable and against a position it judges to be morally unacceptable. How this is done is, therefore, the critical methodological issue. The DEGs elaborated by scientists of the IFOM-IEO Campus aims to fill the present methodological vacuum. Not surprisingly, these guidelines invoke the authority of more than 2000 years of Western culture and thinking, a tradition that is an important part of the heritage of these scientists. They feel that they owe a debt to a society that has, through its generosity, permitted them to perform research into the molecular bases of diseases. They feel the moral obligation to discuss the ethical implications and the sustainability of the procedures and products of their work. They attach one condition: that the discussion be based on arguments and reason.

Accordingly, the main introductory point of the DEGs claims, "We do not wish to propose an ethical code". Such codes frequently lack effectiveness and should not be elaborated by members of a scientific institution in isolation but in conjunction with representatives of the numerous different viewpoints that are present in the society within which the institution acts. What we propose instead are guidelines on how to hold a correct public debate concerning the ethical evaluation of human actions regarding the production and the use of biological and biomedical results. We, therefore, prefer not to start from a preconceived notion of what is morally good, but rather we offer a balanced methodology to structure the deliberative process on what should be permissible on the basis of it being morally sustainable and on what should not be permissible on the basis of it being morally unsustainable. We believe that we can justifiably take on this role, as the deliberative method presented herein is simply a generalisation of the method that has permitted scientific progress and is that which we adopt and implement on a daily basis in our scientific activity. Note that this is not an imposition of the scientific method on ethical practice. Rather the scientific method represents a specific application of the method of reasoning that has characterised and permitted the development of the Western thought since antiquity.

THE STRUCTURE OF THE DEGs

We have indicated above that although there is a debate on deliberative democracy and the term *deliberation* and its cognates appear in many bioethical papers, there is, surprisingly, scarce attention to how to implement and pursue deliberation. On the other hand, the methods and the techniques of deliberation are not taught. We can ask for public engagement in decision making concerning biomedical results, but is the public really capable of coping with deliberation? We have some doubts that this is possible. By taking all this into account, we have decided to fill the methodological gap by setting down guidelines concerning the steps that should provide people with the necessary tools to participate correctly in a deliberative process. We are not concerned now with which people could participate in the deliberation process but rather with the proposal and the diffusion of a model of deliberation. Therefore, the core of what follows concerns guidelines on how to deliberate. We acknowledge, however, that the identification of a constituency of stakeholders is a relevant issue, and we will tackle it briefly in the Perspectives section of the paper.

The history of Western thought contains a rich tradition in deliberation, beginning with Aristotle's *Topics*, *Sophistical Refutations*, *Nicomachean Ethics* and *Rhetoric* and peaking in the medieval universities,[19–21] where at the beginning of his academic career, a student had to attend the Trivium, composed of three subjects: Logic, thought of as the art of reasoning (and, therefore, of deliberating); Grammar, thought of as the art of writing; and Rhetoric, thought of as the art of speaking. Hence, the Middle Ages saw the concrete establishment of the deliberative method that, notwithstanding some reappraisal during the Renaissance[22] and its rediscovery in contemporary age,[23 24] still maintains its validity today.

We built the core structure of our DEGs—the Methodological steps section—by applying the canonical scheme of discussion that was used in the Medieval *disputationes* (disputations),[25–28] with a number of ad hoc pertinent modifications. This standard divided debating into two parts: (1) exposition of the *status quaestionis* and (2) development of the arguments justifying the solution of the question presented in the *status quaestionis*. In turn, the *status quaestionis* was subdivided into five points: (1) concise enunciation of the question to be faced; (2) disambiguation of the relevant terms to be used; (3) clarification of the relevance of the problem in terms of practical and theoretical consequences; (4) critical examination of alternative solutions, to show historical awareness of the problem, of the solutions already proposed and of the reasons why they should not accepted; (5) presentation of the new solution.

Each step of the *status quaestionis* should be self-explanatory. Nevertheless, medieval scholars were taught that before asserting their position (step 5), they had both to clarify the context (steps 1–3) and to show that (a) they were aware of alternative solutions and (b) they had good reasons to refute them. Needless to emphasise, this still constitutes a wonderful lesson for those among us who debate bioethical issues.

If any other medieval scholar wished to criticise the proposed solution, he had to address either the manner in which the *status quaestionis* was presented or the argument offered for the solution. Accordingly, in the methodological core of our DEGs, we have indicated that any objection to an ethical position must address either the justification or the exposition of its *status quaestionis* (that is, it has to follow one of these five avenues: (1) showing that the problem is misposed, (2) showing that the terms are ambiguous, (3) showing that the problem is irrelevant, (4) showing that the alternative solutions are better, and eventually, (5) showing that the new solution is misposed).

It is worth noting, perhaps, that the methodological steps, if correctly followed, can lead to a deliberative consensus if the deliberants have a sufficient knowledge of the scientific issues that are under discussion, a sufficient knowledge of the ethical questions in play and, of course, a sufficient knowledge of how to formulate a rational argument. We have emphasised this point in the guidelines because it is terribly important: the deliberants must know enough to cope with their task successfully. There remains the problem of who or what defines how much knowledge is sufficient. Here, we offer a simple answer: this is dictated by the deliberative context, that is, the level of the deliberative process, the level of the deliberants and the level of those that receive the deliberated results.

The Methodological steps section is preceded by the section Epistemological assumptions. Here, we have defined and delimited the field of the deliberation we are interested in. We have claimed that we discuss the ethical aspects of contextualised human actions in the production and use of biomedical entities and processes but not the biomedical entities and processes themselves. In this way, we emphasise the fact that the subject of an ethical or bioethical analysis is a human action, not a material

object, or a process. For example, we can analyse the production or use of stem cells but not stem cells themselves: stem cells are not the target of a moral judgement, but actions on them are as such; that is, the latter can be morally sustainable.

By the way, note that our use of the term *moral sustainability* serves to emphasise that we do not suggest or indicate any moral position in our DEGs. Rather we advocate that whatever one's moral position, one has to rationally sustain it by means of arguments.

The conclusion of the Epistemological assumptions section highlights that there are differences between an ethical analysis of a human action concerning a biomedical entity or process, its scientific description, its social evaluation and the related legal aspects. These differences should not be neglected for the sake of argumentative clarity.

The Methodological steps section is followed by one called Argumentative paths. Here, we recall some basic points concerning the argumentative paths that may or may not be followed depending on their strength or weakness, validity or fallacy.

Summing up, our DEGs are divided into three sections: the first and the third aim to complete the deliberative guidelines by indicating the epistemological context and the valid ways of arguing; the second, that is, the core section, aims to assert the methodological steps to be followed to ensure a worthy deliberation.

DRAFTING THE DEGs

Four years ago, the Scientific Direction of the IFOM-IEO Campus decided to establish a research and educational branch dedicated to the humanistic aspects of biomedical research. This led to the constitution of a research group on the philosophical foundations of biomedicine and on bioethics and also to the launch of a PhD program on the Foundations of the Life Sciences and Their Ethical Consequences at the European School of Molecular Medicine (SEMM, http://www.semm.it). It did not take long to realise that a stronger engagement of the IFOM-IEO Campus members in the ethical and societal implications of their research was necessary. Thus was born the idea to develop ethics guidelines, which as already mentioned, were deemed to be potentially incisive and effective with respect to the public engagement in decision making.

A small group that had the mandate to prepare a draft worked for 6 months and presented the first version of the DEGs at the scientific council (the assembly of the 50 or so team leaders working at the IFOM-IEO Campus). The draft was discussed in depth, and modifications were proposed, especially regarding the style. After a further three meetings, the scientific council approved the DEGs.

The IFOM-IEO Campus members were invited to sign the DEGs as individual scientists, if they so wished. Virtually, all the scientists agreed, leading to a consensus permitting the implementation of the DEGs, which will be hosted on the IFOM-IEO Campus website. Nevertheless, before taking this final step, it was decided to present the DEGs to an international audience through the publication of a paper in a bioethical journal.

TESTING THE DEGs

Over the 4 years that have spanned the period from the first seed ideas of the DEGs to their approval by the scientific council of the IFOM-IEO Campus, there have been several occasions for putting them to the test in their provisional form. This *in itinere* empirical assessment has allowed, on the one hand, to test the true effectiveness of what we were establishing and, on the other hand, to fine-tune the content and its formulation.

It is worth recalling that the core of our DEGs (the Methodological steps section) mirrors the canon of the rules of debating that was formalised in the Middle Age and that has been used in innumerable theological and moral debates and books where theological and moral *quaestiones* were analysed. In almost all of these instances, there is an explicit reference to the rhetoric architecture previously described. That is, scholars begin with the *status quaestionis* (in its five moves) and then progress to the justification of their thesis; alternatively, if they want to raise an objection, they followed one of the previously indicated alleys.

This same debating canon appears in many good philosophical writing and in many good philosophical debates. This could not be otherwise, for any good philosophical approach needs to present the problem to be faced, clarify the terms that will be used, present reasons to justify the relevance of the problem, explain why available solutions are inadequate and, finally, present the new solution (the five points of the *status quaestionis*). Only then can the solution be justified.

So all in all, our DEGs are not breaking any new philosophical boundaries! They are a simple application to bioethical questions of something that have been tested, in a manifest or latent way, over the past 2400 years. This alone should be sufficient to validate our DEGs. Nevertheless, we have also tested the DEGs as an independent tool that does not require any knowledge of or expertise in the history of Western philosophy from our audience.

One of us (GB) has collaborated for 3 years with the Fondazione Marino Golinelli (http://www.golinellifondazione.org) in a project aimed at establishing a mock parliament in which high school students were trained and invited to deliberate a bill concerning biomedical results.

As part of this project, in 2005, 200 high school students from Genova were invited to deliberate on two topics: genetic screening and genetically modified food. In 2006, the same topics were faced by 120 high school students from Bologna. In 2007, another 120 high school students from Bologna were invited to deliberate on the use of stem cells. In all the three cases, the students eagerly and enthusiastically debated after a preliminary version of our DEGs, with impressive results: the bills they produced as a final act of the deliberative process were well structured, well motivated and extremely liberal (more liberal than the laws provided by our current parliament).

Versions of the DEGs have been presented and discussed during the courses in Rhetoric within the PhD program in Foundations of the Life Sciences and Their Ethical Consequences or during the courses in Ethical Issues within the PhD program in Molecular Medicine at the SEMM. In all the cases, the students were asked to instantiate a debate or to write a paper on selected biomedical issues (animal models, human embryonic stem cells, cybrids, phase 0 clinical trials, research biobanks, etc), using the DEGs to guide their arguments. Needless to say, after a first moment of embarrassment due to the fact that they realised their incapacity of sustaining in a formally correct way a debate or a short talk on a given ethical question, the students showed their satisfaction in being able to reach a deliberative consensus by using only the "weapons" of reason and the disposition to listen to the positions of their fellows, as it should happen in any good deliberative process.

CONCLUSION AND PERSPECTIVES

The proponents are well aware of the fact that the DEGs alone cannot completely resolve methodological feebleness and cultural superficiality of many public debates on biomedical results. The DEGs are, however, intended to present a strong

signal that high-quality debates are achievable, that it is possible to engage the public in a positive way and that we can increase their ethical awareness. However, the DEGs also remind us that all of this can be realised only with solid arguments to fuel the debate, in essence, only if we all use reason.

With this framework in mind, we intend now to proceed and bring the DEGs into the public debate. We will do so initially by exploiting a potent enabling condition developed at the IFOM-IEO Campus, that is, the Science in Society program, and in particular, one of its activities, the IFOM for Schools program (http://www.ifom-ieo-campus.it/sciencesociety/sciencesociety.php). This is a program aimed at spreading and disseminating scientific awareness and sustainability in society. The program targets high school students and teachers. This latter constituency is particularly important because through teachers, we obtain a multiplying effect: through one teacher, we can reach indirectly hundreds of students in their school settings. Although the activities of the program are too numerous to be discussed here, they include educational research fellowships for high school science teachers, theoretical and practical training courses for teachers and students, conferences, development of educational science resources for school practices, open days and summer stages aimed at promoting scientific careers in young people and continuous tutoring and education for teachers. From its inception, in 2002, the program has enrolled 7500 students and 1600 teachers. We will start debating classes in which the rules of DEGs will be taught and implemented. Teachers will be encouraged and provided with incentives to transfer the acquired methodological knowledge into their school classes. Students will be directly challenged to expose themselves in public debates adopting the DEGs. We believe that students represent an important constituency in themselves and a perspective representation of several categories of stakeholders. The above-mentioned pilot experience with the mock parliament bodes well for a large-scale application of the initiative.

Acknowledgements The authors thank the members of the IFOM-IEO Campus, the colleagues, the students and all the people who gave suggestions on preliminary versions of the DEGs. They would like to acknowledge also the referees for their extremely useful comments.

Competing interests None declared.

Provenance and peer review Not commissioned; externally peer reviewed.

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APPENDIX
DELIBERATIVE ETHICS GUIDELINES

The following DEGs were elaborated and proposed by the members of the IFOM-IEO Campus (Firc Institute of Molecular Oncology (IFOM) and the European Institute of Oncology (IEO)). They do not represent the official position of the member institutions participating in the Campus, but rather they are the views of individuals who have freely decided to adhere to the principles spelt herein.

We do not wish to propose an ethical code. Such codes frequently lack effectiveness and should not be elaborated by members of a scientific institution in isolation but in conjunction with representatives of the numerous different viewpoints that are present in the society within which the institution acts. What we propose instead are guidelines on how to hold a correct public debate concerning the ethical evaluation of human actions regarding the production and the use of biological and biomedical results.

We prefer not to start, therefore, from a preconceived notion of what is morally good, but rather we offer a balanced methodology to structure the deliberative process on what should be permissible on the basis of it being morally sustainable and on what should not be permissible on the basis of it being morally unsustainable. We believe that we can justifiably take on this role, as the deliberative method presented herein is simply a generalisation of the method that has permitted scientific progress and is that which we adopt and implement on a daily basis in our scientific activity.

Note that this is not an imposition of the scientific method on ethical practice. Rather the scientific method represents a specific application of the method of reasoning that has characterised and permitted the development of the Western thought since antiquity and that is exemplified in the following guidelines.

The guidelines are composed of three parts:

1. epistemological assumptions
2. methodological steps
3. argumentative paths.

Epistemological assumptions

We advocate that any ethical discussion in the biomedical field should presuppose the acceptance of the following three premises:

i. *What we discuss and judge*
   – The ethical aspects of contextualised human actions in the production and use of biomedical entities and processes.
ii. *What we do not discuss and judge*
   – The biomedical entities and processes.
iii. *What we distinguish between*
   – the scientific description of the biomedical entities and processes;
   – the analysis of the social implications of the actions involving those entities and processes;
   – the ethical discussion and judgement of those actions;
   – the juridical formulation and application of norms for such actions.

Methodological steps

Methodological claim 1

We advocate that any discussion of ethical problems concerning biomedical results be made

- either by presenting a rationally argued solution
- or by rationally criticising an existing solution.

Methodological claim 2

We advocate that any solution to an ethical problem be presented in two steps:

i. Exposition of the ethical problem.
ii. Rational justification of the proposed solution.

Within this,

i. The exposition of the ethical problem is realised by satisfying the following five requirements:
   - concise enunciation of the problem;
   - disambiguation of the relevant terms by defining them;
   - clarification of the relevance of the problem in terms of practical and theoretical consequences;
   - critical examination of alternative solutions, to show historical awareness of the problem, of the solutions already proposed and of the reasons why they should not be accepted;
   - presentation of the new solution.
ii. The rational justification of the ethical solution is made by presenting a rationally cogent argument.

Methodological claim 3

We advocate that any criticism of an ethical solution be made by following one of these avenues:

i. Objecting to the exposition of the ethical problem by arguing that
   - the problem is misposed;
   - the terms are ambiguous;
   - the problem is irrelevant;
   - the alternative solutions are better;
   - the new solution is misposed.

ii. Objecting to the justification of the proposed solution by showing that it is fallacious or weak

Methodological claim 4

We advocate the following three main requirements for a productive ethical debate:

- sufficient knowledge of the scientific entities and processes at hand;
- sufficient knowledge of the ethical questions in play;
- sufficient knowledge of how to rationally justify or criticise an ethical solution.

Argumentative paths

We advocate that any ethical position concerning biomedical results must be argued either through a priori arguments (ie, independently of empirical data or results) or through a posteriori arguments (ie, by considering empirical data and results).

In particular,

- Concerning a priori arguments, those regarding the right to know, autonomy, dignity and quality of life of human beings are particularly relevant;
- Concerning a posteriori arguments, those regarding the positive consequences of biomedical research for human health are particularly relevant. On this point, we caution against the use of two commonly adopted consequentialist arguments: (1) the slippery slope argument and (2) the precautionary principle argument. We consider them to be extremely weak or fallacious.

Epistemological assumptions: commentary

- Biomedical entities and processes are produced and used with the aim of improving human healthcare. Neither the biomedical entities nor the biomedical processes, however, have ethical implications. They serve as the object of biological and biomedical studies, and therefore, are ethically neutral. In contrast, the contextualised human actions surrounding the production and use of biomedical results possess ethical implications. As such, contextualised human actions, and not biomedical results, are the correct target of moral evaluations.
- By contextualised actions, we wish to emphasise that we are not interested in the action per se but in real actions within real contexts. To illustrate this point from a contextualised point of view, the action of inserting a gene into a mouse genome is different from the action of inserting a gene into a human genome, even if the action in itself, that is, the insertion, is the same.

Methodological steps: commentary on claim 4

- Point 1 requires that the participants in the debate who have biomedical training supply sufficient up-to-date scientific information on the issue in question and that the other participants should acquire such sufficient up-to-date scientific information. Discussing the ethics of biomedicine presupposes knowledge of the scientific topics being debated. Of course, sufficient is relative to the particular argumentative context.
- Point 2 requires that the participants in the debate who have ethical training supply sufficient up-to-date ethical information on the issue in question and that the other participants should acquire such sufficient up-to-date ethical information. Discussing the ethics of biomedicine presupposes knowledge of the ethical topics being debated. Of course, *sufficient* is relative to the particular argumentative context.
- Point 3 involves an obligation for all participants to understand the correct form for the debate of the issue in question. Discussing the ethics of biomedicine presupposes knowledge of appropriate debating practices. Take a note that
  - confusing scientific levels with ethical levels is a fallacy;
  - confusing ethical levels with juridical levels is a fallacy;
  - introducing non-justified positions or beliefs is a fallacy.

Argumentative paths: commentary

Remark on the slippery slope argument

The slippery slope argument claims that if an action A occurs, then by a gradual series of small steps via the actions B, C, etc, Z will eventually occur. However, because Z is valued negatively and, therefore, its occurrence is undesirable, A should not be pursued.

Weakness of the argument

If this argument is conceived in such a way that the concatenation of successive actions is necessary, it is a fallacy. No link in the chain of successive actions is necessarily implied by the previous one. Some soften the argument by introducing probability. That would be persuasive if we were capable of assigning a high probability to any passage from A to Z. We cannot do this because we are discussing possible future actions and events situated in possible contexts that are unknown. It should be noted that the slippery slope argument would be very weak even if we were able to establish the high probability of any steps. To illustrate this, if we accepted the argument, we should also admit a symmetrical argument, called the *desirable rack-and-pinion argument*. This follows from the rhetorical rule that if you propone an argumentative structure, you must concede the same argumentative structure to your opponent. The desirable rack-and-pinion argument is structured symmetrically to the slippery slope argument, as it propones a chain of possible actions and events. To distinguish these two arguments, however, the latter starts from an initial action to its possible undesirable consequences, whereas the former begins from an initial action to its possible desirable consequences.

Remark on the precautionary principle argument

According to the precautionary principle argument, if we do not have scientific certainty that the new biomedical results will not harm the environment and that which lives in it, the actions of producing and using them must be cautiously constrained until it is shown they are harmless.

Weakness of the argument

It should be clear that this argument is very vague. It admits many interpretations, ranging from the most radical (according to which we must not perform any action concerning new biological results until we have the full certainty that they are harmless) to the weakest (according to which it is only a commonsense argument, something like "Be cautious when you create or use something if you are unsure about what its consequences will be"). Often, however, the precautionary principle is applied in accordance with an interpretation provided by those in the position of regulating the situation. If these regulators are ideological, the interpretation and the implementation of the precautionary principle is ideological. The real issue should be the level of precaution that must be taken, given the particular problem and its context.