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Anticipating the Interaction between Technology and Morality: A Scenario Study of Experimenting with Humans in Bionanotechnology

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Abstract

During the last decades several tools have been developed to anticipate the future impact of new and emerging technologies. Many of these focus on 'hard,' quantifiable impacts, investigating how novel technologies may affect health, environment and safety. Much less attention is paid to what might be called 'soft' impacts: the way technology influences, for example, the distribution of social roles and responsibilities, moral norms and values, or identities. Several types of technology assessment and of scenario studies can be used to anticipate such soft impacts. We argue, however, that these methods do not recognize the dynamic character of morality and its interaction with technology. As a result, they miss an important opportunity to broaden the scope of social and political deliberation on new and emerging technologies.

In this paper we outline a framework for building scenarios that enhance the techno-moral imagination by anticipating how technology, morality and their interaction might evolve. To show what kind of product might result from this framework, a scenario is presented as an exemplar. This scenario focuses on developments in biomedical nanotechnology and the moral regime of experimenting with human beings. Finally, the merits and limitations of our framework and the resulting type of scenarios are discussed.

KEYWORDS: scenario, technology, morality, ethics, future, bionanotechnology, experimenting with human beings

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In almost all western countries, medical-scientific experimenting with human subjects is subjected to legal regulation. In most cases, the task to judge the acceptability of specific experiments is delegated to institutional review boards or medical-ethical committees. These boards or committees have to safeguard the safety and well being, as well as the rights of human subjects. For example, subjects should be enabled to give their free and informed consent before participating in an experiment. The moral regime to judge medical-scientific experiments and the values guiding this regime seem, by now, quite robust. Is it conceivable that this practice in the future will change? And which role might technological development play in inducing such changes?

Imagine the following newspaper article, dated in 2030:

Monitoring new personalised medical devices

Theranostics (the combination of diagnostic with therapeutic devices) is booming business in medical research these days. Many companies work hard to develop systems that combine implantable sensors continuously monitoring bodily functions with modules for automatic drug release. These devices enable the careful monitoring of one's personal functioning, as well as early, personalised and fine tuned intervention. Moreover, patients can no longer forget to take prescribed drugs.

Recently, however, FDA representatives have warned that the risks of newly developed theranostic devices cannot be adequately monitored by current IRB-procedures. These devices in effect erase the boundary between experimental and regular care: because the devices work in a personalised way, the results of experiments in sample groups need not be informative for subsequent users. In other words: application of personalised medicine will always remain an experimental endeavour.

Consumer and patient group representatives now argue that the rules for experimental medical technology should be extended to all uses of personalised medical devices. They even doubt whether it suffices to monitor *medical* devices only. After all, theranostic systems have been in use to enhance the performance of professional sportsmen and –women for some years already and on Internet applications for cognitive enhancement are offered as well. A spokesman of Glaxo LaRoche, when asked for a reaction, argued just the opposite: if experimenting is the rule rather than the exception, why subject it to separate rules and procedures? The Ministry of Health announced that an expert group will be asked to give advice on the issue.

As this speculative glance into the future shows, novel technologies may not only produce risks for human health and safety; they may also impact social practices and routines, and the moral norms underlying such practices. To highlight this difference, we coined the concepts 'hard' and 'soft' impacts of technology (Swierstra et al., 2009). Whereas scientists are quite willing to anticipate 'hard' impacts, they find it much more problematic to anticipate 'soft' ones (see also Wynne, 2001; Williams, 2008). Elaborate procedures are now in place to check for and prevent a new technology's potential adverse effects on human health and safety. In contrast, tools to systematically anticipate and monitor a technology's impact on social relations and morality are much less developed and, if available, much less used. As a result public and political debate on the desirability of new and emerging technologies in general is quite narrowly focused on potential hard impacts and is framed in terms of quantifiable risk. The recent focus on the risks of nano particles in debates on the desirability of nanotechnology is a case in point.

Technology assessment, in particular ethical Technology Assessment (eTA), and different forms of scenario studies are some of the tools used to explore the potential soft impact of new or emerging technologies on human relations, values and identities. As such, these tools may broaden the scope of debates on the desirability of new and emerging technologies. We are convinced that such tools can significantly enhance the quality of public and political debate by making it more inclusive. However, as we argue in this paper, existing tools to anticipate soft impacts have an important drawback: they hardly acknowledge the mutual interaction between technology and morality (Keulartz et al., 2004; Stemerding and Swierstra, 2006).

Technologically inspired visions of the future often suggest that morality will simply follow technology, implying a 'moral futurism'. Ethical assessments of new and emerging technologies, on the other hand, often judge future technologies with today's moral norms and values, showing 'moral presentism' (Swierstra et al, 2009). Both positions neglect that studies in the history of technology as well as the history of morality have amply shown that technology and morality interact with each other (see for example van der Pot, 1985; Valone, 1998; Miller and Brody, 2001).

This article starts from the assumption that policy makers who want to reflect on the potential impact of new and emerging technologies should recognise the interaction between technology and morality. This is important for two reasons. First, whereas policy makers are now often confronted with ethical controversy regarding an emerging technology, anticipating such effects could help to prepare for and explicitly design public debate on these issues. This might significantly contribute to the democratic quality of deliberation and decision making processes. Secondly, it would considerably broaden the agenda of debates

on the desirability of emerging technologies. Not only the common ‘hard impacts’, but also the ‘soft impacts’ of technology on moral routines and practices would be subjected to explicit ethical debate. Such a more inclusive debate would contribute to the quality of ethical reflection.

In this paper we aim to develop a framework that policy makers could use to anticipate soft impacts of technological development, in particular the mutual interaction between technology and morality. Moreover, we present an extensive exemplary scenario that was built with this framework. This scenario focuses on developments in biomedical nanotechnology and the practice of medical-scientific experimenting with human beings.

We proceed as follows. First, we discuss the advantages and drawbacks of existing tools used to anticipate the ethical impact of new and emerging technologies. We focus in particular on ethical technology assessment (eTA) and on methods for scenario building. Both tools have specific strengths, but they fail to acknowledge the mutual interaction of technology and morality. To remedy this situation, we propose a framework to construct techno-ethical scenarios that acknowledge the interaction of technology and morality. First, we discuss the most important considerations that guided the development of the framework. Next, the three steps of the framework are outlined. Finally, since the proof of the pudding is in the eating, we describe how we used the framework in a pilot study and we present the exemplary scenario constructed using this framework. In conclusion, we discuss the merits and limitations of the proposed framework.

Existing Tools for Ethical Reflection on New and Emerging Technologies

First a note on terminology. In everyday language ‘morality’ and ‘ethics’ are often used interchangeably. In the academic literature they are defined in different ways. For the purpose of this paper we will define *morality* as the set of values and norms that a specific community considers very important, because they refer to legitimate interests, mutual obligations and/or views of the good life. Although the precise boundaries of this set may be contested, morality largely exists in the form of *implicit* beliefs, routines and practices. The embedded moral values and norms only become explicit when they are transgressed, conflict with each other, or are challenged in any other way. At such moments, when moral norms and values lose their self-evident character, ‘ethical issues’ emerge. *Ethics* is the reflection and debate on the relevance and status of (parts of) morality; ethics, that is, is *reflexive* morality (Swierstra and Rip 2007, p.5-6). It is important to note that this reflection is *not* the prerogative of professional ethicists; anyone questioning or debating moral values and /or norms engages in ethical activity.

In modern societies, technological development is an important driver of change. As such, it regularly challenges existing moral routines and thus raises

ethical debate. In view of past ethical controversies on technology it seems sensible, for both policy makers and society at large, to try to anticipate where and how new technologies are likely to raise ethical debate. However, the number of tools to anticipate novel technologies' potential impact on morality is remarkably limited. Since the 1960's many different tools for reflecting and decision-making on new technologies have been proposed. However, most of them were not specifically designed to deal with questions concerning the moral desirability of these technologies (Palm and Hansson, 2006; Smit and van Oost, 1999, Oortwijn et al., 2004). As a result, traditional forms of technology assessment (TA) either simply ignore moral questions or take current moral beliefs for granted (moral presentism) (Swierstra et al, 2009). More recent variants like Constructive TA (CTA, see for example Rip et al., 1995) and participatory TA (pTA, see for example Klüver et al., 2000) tend to equate reflection on a technology's desirability with participation of stakeholders. The question who decides which stakeholders should be engaged, or whether consensus between participants suffices to judge whether a technology is morally desirable, is usually not discussed. This led Palm and Hansson to develop a specifically ethical form of technology assessment, called eTA (Palm and Hansson, 2006).

In addition to this lack of attention to moral questions, many forms of TA are hampered by the so-called Collingridge dilemma (Collingridge, 1980). At an early stage of technology development it is difficult to anticipate and steer the developments, since there are usually many uncertainties and the technology itself is yet fluid; however, at a later stage technology may have stabilised to such extent that attempts to steer its development are no longer effective. Tools like scenario studies and vision assessment were developed to enable assessment and steering at a very early stage (Elzen et al., 2002; Notten et al., 2003; Grin and Grunwald, 2000). Such scenarios may be combined with for example constructive TA (for an example see van Merkerk and Smits, 2007). It has been argued that they can be used for ethical purposes as well (Smadja, 2006).

It seems worthwhile, then, to take a closer look at (1) ethical TA as proposed by Palm and Hansson and (2) scenario methods. While describing their main characteristics, we are particularly interested in the way they deal with the mutual interaction of technology and morality.

Ethical Technology Assessment

Palm & Hansson (2006) present ethical TA as a procedure for identifying and deliberating the moral desirability of new technologies. Like CTA and pTA, it should be conducted during the design process, to enable technology developers to include moral considerations in their decisions. Ideally, it should be undertaken in the form of a continuous dialogue between all relevant stakeholders and the

designers. The central tool is a (preliminary) checklist of issues that may be a source of ethical problems in new technologies. This checklist is based on past ethical debates about new technologies, and is explicitly meant to be neutral with regard to ethical theories (p.551). The list includes moral principles like “privacy”, “sustainability” and “justice”, but it also includes activities or domains of human action like “international relations” or “dissemination and use of information” that do not have normative meaning in themselves but often give rise to ethical issues.

Palm and Hansson acknowledge that this checklist cannot be a definite, exhaustive and fixed summary of existing morality: “Technology often generates new ethical issues that may require innovative thinking for their solution” (p.554-555). Thus, new issues may come up that have not been problematic up to now. Moreover, the meaning of the moral principles on the list is not fixed, because applying them to new technologies may generate new meanings.

Of special interest here is the last issue on the checklist: “impact on human values” (p.555). With this issue, Palm and Hansson do point at the interaction between technology and morality; they explicitly state that technology may affect not only the way we live and understand ourselves, but also our moral values and principles. It may affect the relative importance of different moral principles, and it may change our interpretation of current values. Examples mentioned are that privacy may become less important because of growing accessibility of personal information, and that our concept of human responsibility may change as a result of expert systems supporting human decision-making (p.555). Although they admit that this observation complicates their evaluation, Palm and Hansson do not elaborate this any further. Nor do they reflect on the relevance of this last item on the list for the status of their checklist as a whole. After all, if current interpretations of values are not sacrosanct, they cannot serve as an Archimedean point in ethically evaluating new technologies and the whole enterprise of ethical TA loses force considerably. The observation seems to function mainly as an afterthought to, instead of as the starting point of the eTA-method as a whole. Thus, whereas eTA does focus explicitly on the ethical controversies that a new technology might raise and mentions the dynamic character of morality as well as its interaction with technology, in practice it still conceives of morality as a stable, robust phenomenon. Moreover, it will have difficulties to deal with emerging technologies, since it is explicitly meant as an iterative process of momentary assessments during the development of a specific technology. A final drawback, connected to the former, is that eTA seems to work with a rather limited timeframe, taking small steps at a time. Since morality usually evolves on the long term, this method may have difficulty anticipating such long-term changes.

Scenario Methods

This is different in the method of scenario building. Although scenario methods come in many forms and are used in many contexts with different purposes, the kernel of all scenario methods is that one describes various possible (but not necessary likely) futures, usually in narrative form. Notten et al. (2003) provide a useful working definition of scenarios: “scenarios are descriptions of possible futures that reflect different perspectives on the past, the present and the future.” (p.424) As Notten et al. also indicate, however, the *aims* of developing scenarios, the *process* of designing them, as well as their ultimate *characteristics* may differ to a great extent. Scenarios can be used to explore potential futures or to support decision-making (p.426). In the first case the targeted audience will often be stakeholders or the public at large. In the second case the scenarios will be directed at policy makers. Moreover, scenarios can be designed in an intuitive way, using qualitative information and insights (for example from stakeholders), or in a more formal way, using quantitative knowledge and simulation models generated by experts (p.427). And their content can be relatively simple, focusing on a limited number of variables and actors, or complex, elaborating interconnected events (p.427-428). On all three dimensions, different positions in between are possible as well.

When scenarios deal with the future development of technology in society, technological and social change are often conceived of as variables with at least two potential outcomes. For example, technological promises may come true fast and completely, or only slowly and partly; in the same vein, social acceptance may be fast and enthusiastic, or slow and reluctant only. Combining these variables, four scenarios can be constructed, each of them covering a range of different consequences of specific technological developments. These scenarios may then serve as input for debates with stakeholders or policy makers.

As indicated above, an important advantage of scenarios as a tool for policy making and/or public deliberation is that they invite reflection on long-term changes. The narrative form of scenarios enables one to explore how initial changes might lead to additional changes, and thus to construct convincing narratives of how in the end radical effects might come about. This can be done for emerging technologies as well as for those that have been developed to some extent already.

However, even though both technology and society in this method are conceived of as changeable, morality still is not thought of as dynamic. First, each scenario in itself is usually morally homogeneous. There is not much moral controversy or conflict written into the separate futures. Second, the content of the moral criteria used in the scenarios to explain the enthusiasm or reluctance of the public is not really varied. In scenarios in which technological developments are

applauded, the public apparently thinks these developments might contribute to existing goals and values. In contrast, reluctance of the public is explained by its judgment that the new technology violates existing moral convictions. That moral beliefs might change as a result from technological change is hardly ever acknowledged in these scenarios. Finally, one could of course argue that not the separate scenarios, but their combination and confrontation help to anticipate which issues might become morally controversial. But even then current criteria with which to compare and judge the desirability of the various alternatives are usually taken for granted. To conclude, the scenario method may have definite advantages when compared to eTA, but it usually does not focus on moral controversy and, like eTA, it tends to conceive of morality as a stable phenomenon.

The advantages and drawbacks of both eTA and scenario methods are summarised in Table 1.

	Ethical TA	Scenario methods
Advantages	<ul style="list-style-type: none"> • Enables deliberation on desirability of new technologies • Broad conception of morality • Focus on moral controversy and conflict 	<ul style="list-style-type: none"> • Supports imagination of future • Focus on technology in society • Long term perspective • Applicable to emerging technologies
Drawbacks	<ul style="list-style-type: none"> • Applicable to technologies in development only • Limited time horizon • Morality conceived as a stable phenomenon 	<ul style="list-style-type: none"> • Hardly focused on moral controversy and conflict • Morality conceived as a stable phenomenon

Table 1 – Advantages and drawbacks of existing methods

As the table shows, eTA and scenario methods both have something to offer when it comes to ethical reflection on new and emerging technologies. They might even compensate each other's weaknesses. However, in both cases the dynamic interaction between technology and morality is neglected.

Starting Points for Building Techno-ethical Scenarios

How, then, to acknowledge the interaction between technology and morality when assessing new and emerging technologies? This was the question we posed at the start of a research project we carried out in the past years.¹ The aim of this project was to provide policy makers with a tool to anticipate the soft impacts of novel technologies, in particular their potential impact on moral routines and practices. We agreed that scenario building in general is a useful tool to imagine possible futures and to enrich deliberation processes in advance of decision-making. However, to build techno-ethical scenarios a different methodology would be needed. Our thinking on the type of necessary framework was guided by four sets of considerations.

View of Morality and Ethics

As set out above, we approach morality as the implicit set of values and norms that a specific community considers very important, because they refer to legitimate interests, mutual obligations and/or views of the good life. Ethics, in contrast, is reflexive morality. It is important to note here that this implies a broad view of what ‘moral and ethical issues’ are about. Our framework, like the proposal for eTA by Palm & Hansson, can accommodate consequentialist, deontological, and virtue ethical perspectives on morality, as well as theories of justice. It does not decide beforehand which types of moral considerations are relevant or legitimate.

In addition, our framework explicitly takes its starting point in considerations of *prudence*, that is, the effectiveness of a new technology, the things and activities it enables or disables. Moral philosophers usually consider prudence as a practical, not as an ethical issue, because it deals with the desirability of the *means* to realise a pre-given goal, not with the desirability of the goal itself. In our view, however, philosophy of technology has amply shown that means and goals in technology are closely intertwined (see for examples Swierstra and Rip, 2007, pp. 7-10). As a result, debates on the effectiveness of means are debates on goals as well, and they should be included in an ethical framework.

¹ The research project ‘Developing scenarios of moral controversies concerning new biomedical technologies’ (project leader prof.dr. T. Swierstra) was funded by the Dutch Organization for Scientific Research (NWO), under the program ‘Ethics, Research and Governance’. It aimed to develop a methodology for constructing techno-moral scenarios anticipating the dynamic interaction of technology and morality. Both the methodology and the resulting scenarios were in particular meant for use by policy makers. Further descriptions of both the project and its results can be found in Swierstra et al., 2009; Swierstra 2009; and Stemerding et al., 2010).

Moral Change

The second consideration was that our framework for building techno-ethical scenarios would have to focus on *moral development and change*. This means that it should keep open the possibility of moral change, for example because existing moral principles are interpreted in radically different ways, are weighed differently, or become generally less or more important. In this way, the framework tries to avoid ‘moral presentism’. It urges scenario builders to ask which new moral considerations or which new interpretations of existing ones might come up as a result of specific technological developments. Since moral change is usually not accomplished in short stretches of time, the framework motivates scenario builders to continue beyond the immediate future (next 5 years) into the more distant future (10 – 30 years from the present).

In imagining moral change, however, one should take into account that not all parts of morality change equally quickly. It might be helpful to differentiate between different levels of morality, analogous to the multi-level approach of socio-technical change (Rip and Kemp, 1998; Swierstra, 2004; Stemerding and Swierstra, 2006). On each level morality, change is characterized by a specific pace. Abstract moral principles that have proven their worth time and again, in many different contexts and situations, may be situated on the *macro* level. Examples are non-maleficence, beneficence and autonomy. On the macro level change does occur (the growing importance of autonomy during the 20th century is an example of this), but only very slowly. On the *meso* level moral considerations have materialised in specific institutional practices. These are regulated by procedures and rules, which might be called ‘moral regimes’. At this level the abstract moral principles (like autonomy) are translated into more concrete requirements (like the condition of informed consent). A moral regime usually will display some robustness, but it will change more often than the principles at the macro level. At the *micro* level, finally, very specific moral issues are dealt with in local circumstances, creating ‘niches’ where moral issues can be discussed and negotiated and change will occur relatively frequently. This differentiation should be kept in mind when imagining future moral change.

Anchoring Speculation

The problem with long-term views of the future is of course that they may easily end up in free floating speculation. Our third consideration, therefore, was that the framework should aim for *historically informed* speculations. History comes in at three moments. First, before starting on any scenario of the future, an analysis should be made of past ethical debates and the evolution of moral practices or

regimes relevant to the new or emerging technology. This analysis serves as a starting point from which to anticipate the future.

Next, the positions and arguments generating the imagined controversies should at least be partly modelled on tropes and patterns well known from previous ethical debates on new and emerging technologies. The inventory presented in Swierstra and Rip (2007) offers a valuable starting point for systematically devising plausible arguments. Lastly, historical knowledge is necessary to judge the plausibility of imagined developments. The history of specific moral practices may indicate which parts of morality are relatively robust and which ones are more liable to change. Moreover, it may suggest specific path dependencies in the development of morality. The history of social trends may be used to decide which developments are more or less likely to be widely accepted. By anchoring the techno-ethical scenarios in history, relativist implications may be avoided without succumbing to predictive claims.

Self-reflexivity

The last consideration guiding the development of our framework was that it should incorporate the *self-reflexivity of participants* in debates on the ethics of new and emerging technologies. As Swierstra & Rip (2007) have shown, it is possible to make a list of ‘meta-ethical tropes’ that keep recurring in debates on new and emerging science and technologies. Such tropes concern the status of technology and morality and their interaction in general, like the probability that technological development will prove beneficial, or the belief that attempts to steer technological development will prove futile anyway. Such tropes show that participants are aware that there may be more at stake than just the resolution of the issue at hand. They are grounded, moreover, in deeply entrenched convictions and thus may explain why controversies are so hard to solve. By including such meta-ethical presuppositions or tropes in the scenario, we hope to avoid naivety about the resolution of the imagined debates.

A Three Step Framework

The framework we propose consists of three subsequent steps. First, a thorough analysis is made of the point of departure: what does the current ‘moral landscape’ look like? In the second step, a technological development is introduced and its potential interaction with the current moral landscape is imagined. This usually generates one or more potential moral controversies. In the third step a preliminary closure of these controversies is constructed, based on historical and sociological analysis. The second and third step may then be

repeated several times by inserting further technological developments. This results in scenarios that are more complex and extend further into the future.

In this section the three steps of the framework are outlined. In the subsequent section, we describe how we used this framework to produce a techno-ethical scenario on bionanotechnology and the moral practice of experimenting with human beings. The final section presents parts of this scenario, interspersed with some reflections on the considerations guiding their content. Thus we hope to exemplify how the framework helps to build dynamic techno-ethical scenarios.

Step 1: Sketching the Moral Landscape

To construct a relevant story about possible future(s), a clear view of the starting point in the present is needed. The technological development to be discussed has to be delineated and the relevant current moral beliefs, practices and regulations have to be charted. Preferably the present state of relevant moral practices is given some historical background as well: how did they evolve?

This means, for example, that if one is interested in the future of genetic screening, first the present state of (non-genetic) screening should be described and it should become clear what is and is not controversial in this practice. If the focus is on tissue engineering, it might be relevant to have a look at the present practice of and debates on organ transplantation. It is also possible to start from the side of morality: if you are wondering how a specific moral regime will be affected by future technologies, it is useful to describe how the regime evolved, what is and is not controversial in this regime, and then to decide which technology might destabilize the current regime. This is the case in the example discussed below: the influence of molecular medicine on the moral regime of experimenting with human beings.

Whatever the focus of the historical analysis, this preliminary work should (1) delineate the subject and (2) give one some idea about past and current controversies and how they were solved. Only in this way, one can start wondering how the emergence of new technical possibilities might affect current resolutions and ongoing ethical debates.

Step 2: Generating Potential Moral Controversies, Using NEST-ethics

The aim of this step is to generate plausible ethical arguments and issues concerning a specific new or emerging technology. To this end, we used the inventory of tropes and patterns in past ethical controversies on technology drawn up by Swierstra and Rip (2007), called NEST-ethics (ethics of New and Emerging Science and Technology). This inventory does not focus on the content of ethical

arguments, but on types of ethical considerations and on the formal structure of arguments.

NEST-ethics offers three building blocks for generating a broad range of ethical issues, arguments and debates on new and emerging science or technology. The first sub step is to list the promises and expectations concerning the new technology under scrutiny. What exactly is it that such a technology is said to realise? What does it enable or disable?

The second sub step is to imagine which critical objections might be raised against these promises. Here, the standards central in different ethical theories may serve as a starting point for ethical reflection. Effectiveness, desirability of consequences, rights and obligations, distributive justice, and conceptions of the good life may all offer leads for formulating potential ethical issues. Does this technology really deliver its promises? If so, is the envisaged goal as valuable as is claimed? How to weigh the potential risks and the costs of this technology against its claimed benefits? How are these costs and benefits distributed? How do the technological developments affect existing rights and obligations? And how does it affect current views of the good life?

The third sub step is to construct patterns or chains of arguments: reactions and counter-reactions. Promises of future benefits from a technology are often followed by arguments that focus on its potential drawbacks. They may point out that the claimed benefits are not plausible, that the ratio of benefits and costs or risks is unbalanced, that there are better alternatives to realize the stated goals, or that the claimed benefits are not a benefit at all. A standard reaction of technology developers (and often of policy makers as well) is that further research is needed. Deontological considerations and issues of the good life often come up at a later stage only, when issues about costs and benefits may have been resolved already. Then the goals aimed for by the technology developers may be debunked by critics because, for example, only the happy few will be able to enjoy them, or because these goals do not fit a specific view of the good life. Such arguments may, again, give rise to specific counterarguments. Evoking a certain right or principle may motivate others to invoke alternative, more important rights, or to contest the applicability or the interpretation of the principle in the situation at hand.

This pattern- or chain-building step may profit from the meta-ethical tropes and patterns collected by Swierstra and Rip (2007, pp. 7-10). Often substantial arguments for or against a technology are clothed as or combined with meta-ethical claims. For example, arguments concerning the plausibility and desirability of promised benefits are often modified by presuppositions regarding the possibilities for influencing technological developments. Some will pose that technology in general has proven beneficial, and that technology has usually been able to solve potential ethical problems by technological means. Others will

contest this and state that technology more often than not has led us into disaster. Linked to this debate is the position that technological development is inevitable, and that criticizing it is futile. An example of a meta-ethical trope functioning in good life arguments directed against consequentialist positions is the ‘slippery slope argument’: if we take this first – seemingly innocuous - step, we will definitely go down and lose the possibility to stop technological development later on.

Step 3: Constructing Closure by Judging Plausibility of Resolutions

In the third step the multitude of potential (counter-)views and (counter-)arguments generated in step 2 has to be reduced by imagining which resolution might be plausible. How will opposing arguments be weighed? The aim is not to judge which resolution would be ‘rational’, but to imagine which direction of the debate and of decision-making is plausible, considering past solutions and actual trends in morality. In this phase, controversy is brought to a temporary and often partial closure.

The first question to ask is which parts of morality have proven robust in the past. As discussed above, it is useful to distinguish between three levels of morality in society. In constructing closures, scenario writers should take into account that moral change is most likely to occur on the micro level of local decision making, creating a ‘moral niche’. Evolution of a moral regime at the meso level is more plausible if a niche has proven very successful; when, for example, it is perceived as an example of ‘good practice’. Changes on the macro level of moral principles will take even more time.

A second way to determine the plausibility of specific techno-ethical developments is to look for long-term evolutionary trends in society (like for example individualization or democratisation) or path dependencies (in which solutions that worked well in slightly different contexts are relocated to novel contexts) or potentially analogous situations (Trappenburg, 2003; Swierstra et al., 2010). If a specific change fits well with such trends or if analogies can be found relatively easy, it is more plausible that such changes will occur.

The closure eventually proposed in a scenario may be explained by technological developments, for example if a promise does not come true or is feasible only at very high costs. Or it can be based on moral developments, for example when it is decided to introduce a specific technology or to change procedures for regulating it. From this point onwards, step 2 and 3 may be repeated several times, to construct a long-term scenario.

Of course, closure does not always mean that ethical debate will be completely silenced. Even if the scenario builder decides that it is unlikely that major changes in morality will occur, it is still plausible that a minority of

stakeholders will continue to object and to bring forward counterarguments. This may result in an ongoing dynamics that informs subsequent parts of the narrative.

Moreover, constructing closure always implies the introduction of some contingency. Although step 3 is meant to generate a well-considered judgment regarding the plausibility of a specific closure, necessity will be lacking. In addition, although techno-ethical scenarios are explicitly designed to focus at the interaction of technology and morality, these are not the only forces driving human history. Other sources of contingency (like the political colour of the government, or accidents that strongly influence public opinion) do play a role and including them in a scenario will increase its plausibility. To highlight the unavoidable contingency of imagined future developments, scenario builders can decide to construct two (or even more) closures of a specific controversy, after which the future may diverge in different directions, and alternative futures may be imagined.

Building a Scenario with the Framework

In the remainder of this paper, we will describe how we used the framework outlined above to develop a techno-ethical scenario on the interaction of bionanotechnology and the moral practice of experimenting with human beings. We chose bionanotechnology because it is a rapidly developing field, currently attracting a lot of attention from policy makers and technology assessors. To our knowledge, however, the potential impact of this field on morality has not yet been investigated. Bionanotechnology is actually a cluster of emerging technologies, most of them as yet consisting of promises and basic research (see for example Malsch, 2005; de Jotterand, 2008). Since concrete applications are relatively rare, we decided not to focus on moral controversies concerning potential applications, but on moral controversies in the R&D phase. More specifically, we focused our scenario at the interaction between *biomedical* nanotechnology (or molecular medicine, see Boenink, 2009) and the moral practice of medical-scientific experimenting with human subjects. The question guiding us here is: *how might developments in molecular medicine affect existing moral practices concerning medical experiments with human beings?*

First, we performed a literature survey to get an overview of the type of technologies involved, of current possibilities as well as expectations regarding future applications.² The hopes and ideals guiding technological developments in

² Documents that proved particularly useful were: CTMM Working Group (2006), European Group on Ethics (2007); Fortina et al. (2005); Health Council (2006); Johnson and Evans (2002); Malsch (2005); Pagon (2002); Roszek et al. (2005); Singaleringscommissie Kanker (2007); TA-Swiss (2003); TWA Netwerk (2006); Wagendorp (2007).

molecular medicine received particular attention. We also collected literature on the ethical issues put forward in relation to molecular medicine. The first step in preparing for a techno-ethical scenario (sketching the moral landscape) consisted of an explorative survey of the history of medical experimenting with human beings. This history is of course partly international, but we paid special attention to the evolution of this moral practice in the Netherlands, since the scenario would be located in this country as well. To get a good view of the preceding controversies, we did not only look at the resulting changes in regulation, but also at the ethical debates that accompanied this evolution. Finally, we specifically analysed how technological developments had impacted the evolving morality of medical experiments with human subjects.

This gave us a starting point for performing the second step of our framework: the exploration of future changes of the moral landscape that might result from developments in molecular medicine, as well as the influence of the moral landscape on technological developments in this field. As indicated above, we used NEST-ethics as a tool to systematically generate ethical controversies. To broaden the input for this phase, we first organised an interactive workshop with Dutch policy makers and experts in technology assessment who had worked on bionanotechnology³. During this workshop, we brainstormed about potential controversies with regard to this group of technologies and the practice of experimenting with human beings. The tropes and patterns of ethical controversies identified by NEST-ethics were used during the workshop as a stepping-stone to systematically generate and structure ideas (which at the same time provided us with feedback about the heuristic value of this tool). The results of the workshop were then further developed and elaborated during discussions between the researchers involved in the project.

The third and last step of our framework, constructing closure of the raised controversies, was also largely carried out by these researchers. Step 2 and 3 were often conducted simultaneously, because they need to be reiterated to develop a long-term scenario consisting of several phases. To judge the plausibility of specific closures we used the previously conducted study of the history of medical experimenting with human beings, for example by identifying path dependencies that might be repeated in the future. This study also gave us some clues as to the relative robustness of different parts of current morality. In addition, we used our knowledge of basic social trends to check the plausibility of suggested developments.

The first draft of the scenario was written by the first author of this paper and then repeatedly discussed with the other authors, leading to several redrafts and discussions. It quickly became clear that the tropes and patterns of NEST-

³ We also invited scientific experts working in bionanotechnology, but unfortunately none of them was able to attend.

ethics easily lead to a proliferation of potential ethical issues and arguments. Including them all would lead to very extensive scenarios, with a lack of focus. The decision to include specific controversies and to exclude others in general will have to be determined by the goals of a particular scenario project. Since it is our goal here to show how our framework can be used to generate techno-ethical scenarios, we decided to construct a scenario with four subsequent phases, each of which focuses on just one type of moral change or controversy. These are: the destabilisation of moral routines by new technologies (phase 1), ‘rule ethical controversies’ about rights, obligations, responsibilities and justice (phase 2), controversies about the boundaries of conflicting ‘rule ethical’ regimes (phase 3), and ‘life ethical’ controversies about issues of identity and the good life (phase 4). This choice clearly serves analytic purposes; in real life, of course, different types of controversies usually occur simultaneously. The four phases are preceded by a summary of the existing moral landscape of medical experimenting with human beings in the Netherlands (phase 0).⁴ For this publication, each phase is preceded by a reflexive passage (in *italic*), to elucidate the connection between the three step framework and the actual narrative content.

The scenario fragments and the reflexive comments together may function as a ‘proof of principle’ for the claim that our framework helps to produce dynamic techno-ethical scenarios. This proof of principle might then be elaborated and tested in different contexts by others.

A Techno-Ethical Scenario: Imagining the Future Of Medical Experimenting With Human Beings

Phase 0: The Dutch Moral Landscape of Medical Experimenting with Human Beings Anno 2010

Here the first step of the three step framework is carried out: sketching the existing Dutch moral landscape of medical-scientific research with human beings. In the Netherlands the potential conflict between the benefits of medical research and the burdens, risks and rights of human subjects since 1999 has been pacified on the macro level by the Law on Medical-scientific Research (in Dutch the WMO). On the meso level of the institutional review boards, informed consent and the balance of benefits and burdens/risks are important criteria to determine whether research is morally acceptable. However, the emergence of biobank research in the new millennium has raised questions regarding the meaning of concepts like ‘burden’ and ‘risk’ and regarding the interpretation of informed

⁴ The whole scenario is situated in the Netherlands, but citizens of other western countries will probably recognize the main issues and controversies as well.

consent. Two professional codes for biobank research published in 2002 and 2004 settled the matter at the meso level, at least temporarily.

In any practice of experimenting with human beings at least two values have to be balanced: the value of human beings and the value of scientific and medical progress. In the Netherlands, a Law concerning Medical-scientific Research (in Dutch: Wet Medisch-wetenschappelijk Onderzoek, WMO), regulates this balancing. The law was instated in 1999, formalising a practice that had evolved during the preceding decennia. It requires medical-scientific researchers to submit their research protocol to an authorised institutional review board (in Dutch: Medisch-Ethische Toetsings Commissie, METC) if the research involves actions that might violate a person's physical or psychological integrity. The METC evaluates whether the experiment is *scientifically sound*, whether the *potential benefits* of the research justify the *potential burdens and risks* to the human subjects, and whether these subjects can make an independent decision whether or not to participate on the basis of correct and complete information (that is, by *informed consent*).⁵ Research that is particularly controversial and/or for which specialist expertise is needed has to be submitted to a national review board (the Centrale Commissie Mensgebonden Onderzoek, CCMO). Anno 2010, approval of research using for example germ cells, foetal or embryonic material, or cell therapy is the CCMO's prerogative.

At first the new law seemed to succeed in bringing previous debates to a closure. At least the criteria with which the legitimacy of specific research had to be judged by METC's and CCMO were no longer contested. However, in the wake of the Human Genome Project at the start of the new millennium, a novel type of medical research evolved. By collecting blood or tissue from large groups of citizens in 'biobanks' and then linking these to their medical files and genealogical information, researchers aimed for increased knowledge of the relation between genetic characteristics and health or disease. In the Netherlands no prospective population biobanks were set up, but similar (retrospective) research was proposed with body material from specific patient populations.

This new kind of genomic research raised the issue how to deal with the informed consent-requirement in the WMO. The medical researchers argued that it would be impractical and unnecessary to ask for a participant's informed consent *each time* his or her body material would be used, although the WMO seemed to require this. It might be very difficult to receive informed consent years after a patient initially donated the body material. Moreover, the blood and tissue

⁵ These criteria largely coincide with the criteria used in comparable laws in other Western countries. See for example for the American situation: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=56.111> (accessed June 18, 2009).

included in biobanks usually would have been collected for purposes of care, that is, in the patient's interest, in the first place. Using it for biobank research would not put an additional burden on the patient.

However, some moral philosophers and lawyers argued that participating in such research might not be physically burdensome, but could be harmful in other ways. Since these databases would contain private, personal information, misuse might violate a subject's privacy. It would be a mistake, then, to exclude biobank research from informed consent requirements: subjects should have a right to be protected against violations of their privacy.

In response to questions in Parliament, the Minister of Health in 2001 promised to produce a paper on the acquisition and (subsequent) use of body tissue for the purpose of scientific research. This might lead to a new Law on the Authorization of the Use of Body Material. However, it proved difficult to make such a law cohere with existing laws on medical research with human subjects, on patient's rights and on privacy protection. As a result, the project did proceed very slowly (Ministerie van VWS, January 17, 2002 and September 7, 2007).

Meanwhile, the Federation of Medical-Scientific Associations (FMWV) decided to take action. In 2002 it published a professional code on the use of body material. In 2004 a professional code on the use of information from personal medical files for research followed (see <http://www.federa.org/?s=1&m=99>). Both codes state that individuals should be enabled to give or withhold informed consent for the use of their body material and/or information from their personal medical files. However, they also state that a once-only declaration of 'no objection' suffices if the data will be anonymised or coded, and if the research is retrospective only.

Public debate on the codes is almost absent, probably partly because there are no plans for huge, nationwide biobanks in the Netherlands. Incidentally, a lawyer and a moral philosopher did publish on the issue, but they are lonely wolves. The lawyer focused on issues of psychosocial burdens, privacy and property (Dute, 2003). The moral philosopher suggests that issues of justice should be considered as well (Swierstra, 2004). After all, if research consortia or medical companies are able to arrive at new insights and products on the basis of tissue acquired from other persons, these persons might have a legitimate claim to share the benefits of the research. This suggestion, which might radically change existing practices of medical research with human beings, didn't receive much attention, however.

Dutch genomics research largely focused on the morally less cumbersome retrospective linking of genetic make up and medical history. Soon enough, the first results of the quest for 'biomarkers' were announced: a DNA chip enabling improved prognosis for breast cancer patients (van 't Veer et al., 2002). Following this initial success the Dutch academic medical centres agreed to connect their

local biobanks to create a huge resource for biomarker research. This cooperative biobank (poetically labelled ‘String of Pearls’) will cover data from academic hospitals throughout the Netherlands. It will include body material from patients with a disease in one of eight pre-defined areas, who primarily donated this material for clinical purposes. Moreover, it will be a virtual biobank: standardization of tissue storage and of the way data are registered should enable interesting comparisons. Work on this project started in 2007 (www.string-of-pearls.org).

The String of Pearls-project works with anonymous data only. Therefore, according to the existing professional codes, a ‘no objection’ policy is sufficient. Thus, because of the huge scope of the project, in the future a substantial number of Dutch patients may be asked whether they object to further, anonymous use of their body material for the purpose of medical scientific research.

Phase 1: Biomarkers and Datamining (2010-2012)⁶

Starting from this moral landscape, the next phase illustrates how future moral controversies and temporary closures can be imagined (step 2 and 3 of our framework). More specifically, this fragment shows how technological developments may destabilise the existing moral landscape by creating a ‘niche’ at the micro level. First, these developments make explicit the robust moral routines guiding the practice of medical experimenting with humans. In doing so, they open them up for criticism. A controversy concerning the meaning of consent and privacy in the context of this new type of research ensues. The controversy is closed when the ‘no objection policy’ implied in the professional codes (meso level) is endorsed by a legal verdict (macro level). Thus technological developments induce changes in the moral practice of experimenting with humans, and this in turn generates a new moral regime in which retrospective and prospective biobank research becomes morally relevant.

The story starts when the Dutch Minister of Education and Sciences, a former genomics scientist, is pressed by his former colleagues to clarify the current ambiguous regulation of research with body material. After all, the search for biomarkers has dramatically intensified in recent years, and Dutch researchers fear they will lag behind if they are hindered by current regulations. They add that this type of research will continue abroad anyway, like research in general tends to do.

When the Minister proposes to alleviate the obligations of researchers in the field of genomics and molecular medicine, however, he finds himself opposed

⁶ From here on, the story is completely fictitious, although it is inspired by real persons and events, as well as based on current literature on bionanotechnology mentioned in footnote 2.

by the Minister of Health. She argues that medical science and technology should be developed very carefully, with respect for the human beings involved. Moreover, the professional field seems to have done a good job in self-regulation; the codes for good practice are widely accepted. Furthermore: prospective, non-anonymous research is not exactly forbidden. It may be more cumbersome, but this is only the price to be paid for social acceptability.

Minister: molecular medicine is the future

The Minister of Education and Sciences today endorsed current Dutch initiatives to investigate the relation between changes at the molecular level of the body and health or disease. “Investigating DNA characteristics, their translation into RNA and proteins is not just important for scientists who are curious how the body works. It may also help us intervene as early as possible in disease processes, and thus prevent or reduce a lot of suffering.” The Minister spoke at a conference of the Dutch Centre for Molecular Medicine, a public-private partnership set up in 2007 with a grant from the governmental innovation budget. Another grant from this budget was awarded to the Pearl String Initiative, a cooperation of the eight academic medical centres to link their databases for research purposes. Researchers involved expect that the first results from these projects will become available soon.

In *NRC Handelsblad*, February 21, 2010

In April 2011, researchers involved in the Pearl String Initiative announce that they have found an important biomarker for Alzheimer’s Disease. Representatives of the Alzheimer Foundation write a letter to both ministers involved and publish a piece in the newspaper *De Volkskrant*, in which they contest the requirement to anonymise all data in biobank research. As the recent discovery shows, they argue, such research produces important medical knowledge that is immediately relevant to the individuals involved. Shouldn’t those who consented to inclusion of their tissue and medical file such biobanks also be the first to reap their benefits? This requires, however, that the relevant participants can be personally identified. Since the decision to make all data anonymous was allegedly motivated by current regulations, the patients’ representatives urge the Ministers to change the law and enable research with personalised data using a ‘no objection’ system. The issue is brought to a head in September 2012.

Patient: tissue should be removed

Mr. H. from A. today in summary proceedings asked for immediate removal of his brain tissue from the lab of the Academic Medical Centre in A. He argues that he was not adequately informed that the brain tissue he donated might be used for behavioural genetic research. He donated the tissue to enable a diagnosis of potential brain tumour (which luckily turned out to be negative). Mr. H. says he objects to behavioural genetic research because history has shown that it may easily lead to discriminatory policies. Moreover, he argues that he was only given the opportunity to object to the re-use of his tissue for research purposes in very general terms. In a public statement he claims that he goes to court “because I think everybody should be offered the opportunity to indicate for which type of research his or her bodily material may be used. This way, the public can influence the direction of scientific development. The way donating tissue is organised right now means that one can only consent or object to biomedical scientific research as a whole.” Judgment will be passed in two days.

From: *de Volkskrant*, September 30, 2012.

The case is decided in favour of the academic medical centre because the patient was given opportunity to object to *any* scientific use, which includes behavioural genetic research. Moreover, the centre acted in line with the professional codes. Thus, the practice implied by the professional codes is legally endorsed and becomes accepted by most non-professionals as well. Visitors of Dutch academic hospitals become accustomed to ‘no objection-forms’ quite soon, usually deciding to donate their body material for research. An unplanned and unforeseen result is that Dutch biobank researchers continue to focus on retrospective work, since this is much less cumbersome to organise than prospective research.

Phase 2: Point of Care Applications (2013-2017)

This section shows how further technological developments disturb the preliminary closure sketched above and raise subsequent moral controversies (step 2 of our framework). The section focuses specifically on ‘rule ethical’ controversies concerning rights, obligations, responsibilities and justice. The development of ‘point of care devices’ relocates research from lab or hospital to daily environments. This blurs the boundary between research and care, as well as the roles and responsibilities of researcher/caregiver and experimental subject/patient.

The specific closure constructed here (step 3) seems plausible because it is a compromise between the individual responsibility of the user that is increased

by these devices anyway, and the responsibility of the researcher. Moreover, it is modelled on the role of the independent medical advisor that is already required in medical experiments (moral path-dependency).

The rise of nanotechnology during the first decennium of the century has not left the medical field unaffected. For a start, it is now possible to measure very small concentrations of specific molecules. This has significantly improved the sensitivity of biomarkers based on proteins and metabolites. Secondly, the equipment needed to analyse body material has been radically miniaturised. Lastly, the amount of body material necessary for analysis has been minimised. This rise of what is called ‘molecular medicine’ has stimulated and enabled researchers and engineers to develop small diagnostic and monitoring devices to be used in very different contexts. These so called ‘point of care applications’ can be used in the GP’s office, at the bed side in the hospital, or even at home as a self-test. Examinations formerly conducted in a lab by medical professionals, now can be conducted by non-specialists or even lay people.

As a result both the focus and the location of experimental research on biomarkers shift: researchers now aim to establish the usefulness and reliability of these new molecular diagnostic devices in GP-offices and at home. Experimental research with such molecular diagnostics thus moves out of the lab and hospital. In this type of research it is hardly useful to code diagnostic results, since the point of the new devices is that they make these results immediately available to users. Therefore, experiments with point of care applications are subject to the regime of the Law on Medical Scientific Research, and full informed consent of participants is required.

A home test for colorectal cancer

Within some years, it may be possible to regularly test yourself at home for colorectal cancer. Researchers of the Centre for Translational Molecular Medicine in Eindhoven yesterday announced that they have developed a biomarker chip that can be used by lay people. The chip needs just some drops of blood to indicate the level of a specific protein. If the protein level is too high, this may indicate the onset of colorectal cancer. “The chip is designed in such a way that it is easy to use for anyone. It may be especially useful for members of families with a high rate of colorectal cancer” says dr. de Bruin, one of the researchers involved. The chip is not on the market yet. Clinical and usability tests will start this year. Approval for the Dutch market is not to be expected before 2016. A home test for detection of heart attacks will shortly become available as well, a representative of CTMM said.

In *Diagned* (monthly magazine of the Dutch medical devices industry), May 2014.

The new devices raise new ethical questions. These relate to the shift of roles implied by point of care applications. If these devices produce information on the spot instead of in the lab, who can be held responsible for the correct interpretation of these results? What are the rights and obligations of subjects and researchers/clinicians?

Controversy first focuses on the issue whether or not subjects should be informed of the test results. A group of critical medical professionals suggests that subjects in experiments with point of care applications should not be informed of the results at all, since the technology is still experimental and the meaning of results is not yet clear. The research is meant to contribute to scientific knowledge, not to the patient's welfare. Any suggestion to the contrary would be misleading and produce false certainties. As researchers quickly point out, however, research and care cannot always be clearly separated. The biosensor for colorectal cancer, for example, is designed to facilitate use by non-professionals, and its results (expressed as normal, high, low, or extremely high/low) can be clearly read from a display immediately after measurement. This is exactly one of the features that should be tested: are patients able to use the device correctly and to interpret the results? So patients have to be confronted with their personal results anyway.

The association of families with hereditary colorectal cancer adds that subjects have a right to know the result, even if the device is still experimental. It may be their only way to a timely cure, since endoscopy (the traditional diagnostic procedure) is not infallible either. The association points at a precedent in the nineties of the last century. When DNA marker tests for Duchenne's disease were developed, research activities and diagnostics were first strictly separated. Research subjects were not told their test result because the DNA test was experimental. After pressure from the families involved, however, experimental marker tests were offered for diagnosis more quickly (when they produced a reliable result in 95 % of the cases). Why not follow this example for the new point of care applications as well, the association asks.

A moral philosopher argues that if these devices are designed to produce results for users, it is hardly relevant to talk in terms of 'a right to know' or 'not to know'. Users will have to know results anyway. A more relevant question is: how to make sure that users understand and interpret these results correctly? Although most users will be able to read the results from the display, not all of them will have the knowledge and the ability to grasp their meaning. Even highly educated people may have difficulty to do so. After all, as long as a device is experimental the reliability of results is unclear. Moreover, technologies aiming for early diagnosis in particular may produce a high number of false positives. Follow up diagnostics (for example in the form of endoscopy) will then be necessary to produce a clear, meaningful result. Intricacies like these, the moral philosopher

argues, make professional help in interpretation indispensable. Instead of a ‘right to know’, a ‘right to receive professional help in interpreting results’ should be claimed.

The controversy is not brought to a clear end, resulting in a variety of solutions at the micro level. Institutional Review Boards follow very different policies; each one drawing its own line. In some experimental projects efforts are made to prevent users’ direct access to the result. When subjects do have direct access some projects appoint specific medical professionals to help users interpret results. Others refer for this task to the subject’s GP. Such help is sometimes obligatory, at other times only available on request. In some projects, mainly those investigating low-tech devices for less serious diseases, no help at all is available.

Then, in 2016, the controversy suddenly revives because of a tragic incident:

Suicide after home test

A man participating in an experiment with a self-test for colorectal cancer has committed suicide. He apparently concluded from the test that he had cancer, which he associated with severely reduced quality of life and an inevitable, painful death. The researchers involved have expressed their regret. The man was expected to discuss his results with them the day after his suicide. The project leader stated that all participants in the experiment have been informed in advance that the test does not produce certainty. The Central Review Board for Medical Scientific Research has started an official investigation.

NRC Handelsblad, December 23, 2016

The suicide causes moral outrage: shouldn’t this man have been protected from this information, or shouldn’t he at least have had some professional help in clarifying the exact meaning of the result? How could he have known that the result may have been a false positive, and that colorectal cancer usually responds very well to therapies, so that it is not lethal in the majority of cases? The Minister of Health (member of the Liberal Party) acknowledges that there may be a problem with these ‘point of care’ devices. He is reluctant to deal with this problem by a change of law, however. Requiring counselling of subjects in all experiments with point of care applications would be way too paternalistic, the Minister says. He does promise, however, to encourage the parties in the field to develop a policy to prevent awful events like this suicide.

After several meetings of researchers, patient organizations and companies involved, in 2017 a protocol for experimenting with point of care devices and self tests is developed. It states that researchers and companies experimenting with these devices should always offer subjects help in interpreting the meaning of

results. If the test is for a serious disease (like cancer), help is obligatory and should be given by an independent medical expert. Since all medical research on human subjects is already obliged to hire an independent medical advisor who is available to discuss pros and cons of participation with potential subjects, this construction should not cause too much practical problems for researchers.

But before the ink of the agreement has dried, a scientist in *de Volkskrant* points out the irony of the situation. The unreliability of biomarker tests, he argues, is mainly a result of Dutch regulations concerning prospective biobank research. Since the professional codes require full informed consent in case of prospective research, this type of research is rare in the Netherlands. Without prospective research, however, the reliability of new biomarker tests will remain questionable. To improve the quality of point of care devices, he argues, we should lift the restrictions on prospective research.

Phase 3: Wet Sensors and Data-Warehouses (2018 – 2023)

This section explores how technology, when restricted by the current moral landscape, might develop in unexpected directions, thus blurring the boundary between medical and non-medical experiments with human bodies. This generates a novel type of moral controversy (step 2): why protect subjects in the first, and not in the second case? The preliminary closure constructed here (step 3) implies that a new type of regulation, applying to both domains, is formulated. This closure seems plausible because it follows the pattern of earlier changes in the domain of application of such regulation: usually the domain considered in need of regulation is extended, instead of limited (for example in case of behavioural science research).

In due time, a new technological solution to the reliability problems of molecular diagnostics emerges. For some time now, researchers have been working on miniature sensors that can be implanted under someone's skin or ingested: so called 'wet sensors'. These sensors are usually combined with RFID-chips that send the data collected by the sensor to an external computer system. Reading devices enable researchers to collect data on a person's functioning without personal contact, even without this person noticing anything. The data may then be stored and analysed in a huge 'data-warehouse'.

One of the big advantages of wet sensors, the involved researchers state, is that they enable continuous monitoring of individuals, as well as the construction of personal patterns in bodily functioning. This may contribute to early diagnosis. And it may solve part of the interpretive problems of self-test kits, since interpretation of results is less difficult if these results can be compared to personal patterns. Wet sensors might even enable a radical personalization of

diagnosis and therapy, the researchers claim. However, development of such wet sensors has been seriously slowed down because these devices have been subjected to the same kind of regulation as drugs. If we want to solve the reliability problem of current diagnostic devices, these researchers state, the restrictions on research with in vivo devices using nano particles (in place since 2012) should be lifted.

The plea to weaken the rights of experimental subjects meets with resistance. Patient organisations argue that such a weakening would be the first step on a slippery slope. Participants in medical experiments should be protected, and as long as research is not made completely impossible, researchers will have to put up with these democratically approved requirements.

Biomonitoring of top sportsmen

Researchers from the University of Nijmegen have developed an ingestible sensor for top sportsmen. The sensor is able to regularly measure several physiological parameters and send the results to a distant computer. The data and patterns produced indicate whether someone has used doping. An important advantage of this system compared to the biological passport used now, is that the sports(wo)man can go wherever s/he wants. Functions can be read anywhere anytime. This helps to prevent tampering with bodies and finally guarantees fair competition. The sensor will be tested in this year's Dutch Amstel Gold Race. The World Anti Doping Authority and the International Cyclists Organization both have expressed their interest.

In *Sportsweek*, May 14, 2018

The first 'real life' experiments with humans using molecular wet sensors are performed in sports. Here the strict regulation of medical experiments with human beings does not apply. Moreover, extensive monitoring of heartbeat, blood sugar level and other bodily functions has been common practice in professional sports for years. Such monitoring has been considerably reinforced by the war against doping. The World Anti Doping Agency from 2008 onwards subjected professional cyclists to obligatory monitoring of their blood and urine, resulting in a 'biological passport'. Deviations from the patterns collected in the passport were interpreted as proof that a sportsman had tampered with his body. Since 2008, most other branches of professional sports followed suit.

The resulting bureaucratic control system is quite burdensome to the professional sportsmen/women and their medical supervisors. Additional parameters kept being added to the passport, while the number of doping checks also increased. Moreover, organizations of professional sportsmen, in particular

the cyclists' union, kept protesting that the passport undermined the privacy of the sportspeople, since their whereabouts had to be monitored as well. As some scientists and engineers are now quick to observe, wet sensor technology is able to offer a solution, since it enables monitoring from a distance (no more need for whereabouts) in a way that hardly burdens the sports(wo)man.

Researchers from Nijmegen cooperate with the organisers of the Amstel Gold Race (a Dutch cycling tour) to test a wet sensor system. This causes some concern. Scientific colleagues are appalled that the organizers did not submit their experiment for ethical review. After all, this is about human beings and their health; using devices of unknown quality and effect means that the participants are subjected to potential risks. A group calling itself 'Medical Scientists for Fair Play' argues in the widely-read medical journal *Medisch Contact* (Medical Contact) that sportsmen may not be in as weak a position as patients are, but that they still need protection. The freedom of sportsman, like the freedom of patients, is easily infringed upon. In the future, a refusal to have a wet sensor implanted may be interpreted as suspicious and might endanger one's career. And if experiments with wet sensors in sports are hampered by moral intricacies similar to those in the medical domain, the group argues, it makes sense to extend the regulation of experiments in the medical domain to non-medical experimenting with bodily technologies. Their protests are hardly noticed.

Wet sensor technologies are developed in other contexts as well. In 2020, the SugarMonitor™ is introduced in the USA, and soon afterwards in several Asian and European countries. This implantable sensor monitors one's blood sugar level. Personal data are sent to a computer for analysis. The system issues a warning if one's blood sugar level is below a certain threshold. Since research has shown that a low sugar level causes serious lapses in concentration, the producers of the SugarMonitor™ advertise the system as 'enhancing your cognitive achievements'. The sensor is quite expensive, though, and for the first years is mainly a 'must have'-gadget for the rich.

A physician closely involved with the Dutch Diabetes Association accuses the producers of the SugarMonitor™, which until recently specialized in medical sensors, of cynicism and immoral behaviour. He says the device was originally intended for people with an increased risk of diabetes. However, since the regulations for medical wet sensors are very strict, it would take a lot of time before the device could be introduced on the market. According to the physician, this was the reason why the firm decided to promote the sensor as an instrument for non-medical purposes. In effect, she argues, this means that people who use the sensor for cognitive enhancement are exposed to risks that might be considered irresponsible when the sensor would have been used for monitoring diabetes patients. The lawyer of the firm in a reply points out that the firm has not

violated any law. The SugarMonitor™ has been subjected to all the necessary tests and safety checks required for consumer products.

A more general debate ensues about the domain to which regulation of experimenting with human beings should apply. Isn't it outdated to limit regulation to medical-scientific experiments only? The risks and interests may be at least as big in other domains as in health care. Moreover, the boundary between health and human functioning in general is not as clear as regulation presupposes.

Now several medical researchers, frustrated for years by the legal restrictions on medical experimenting, seize the opportunity. Why, they publicly demand, should risks that are accepted in non-medical settings be banned from medical research? The comparison with sports only shows that the risks involved in experimenting with the body may be acceptable if some valuable benefit is to be gained – and isn't the promise of (continued) health even more valuable than the promise of fame? Why then be so protective and paternalistic towards potential subjects of medical experiments? In the case of monitoring we are talking about healthy people, not even about patients weakened by disease. Moreover, there is no risk of role confusion as when physicians are also researchers. If information is balanced and correct, including the uncertainties regarding risks and benefits, healthy individuals should be considered perfectly capable to decide for themselves whether their health warrants a small risk of harm. Autonomy and informed consent, that is, should be more important than precaution to do no harm.

Opponents retort that this is precisely the problem: how to provide potential subjects with correct information if hardly anything is known about what wet sensors in a human body do? In addition, the permanent and almost invisible character of wet sensors poses new problems concerning consent and privacy. Is it sufficient to ask for consent once, before a sensor is implanted or ingested? Or should it be repeated regularly, to remind subjects of what is being done to their bodies? And how to guarantee that the data collected are used for the subject's well-being only? It might be in the interest of employers and teachers, for example, to stimulate use of the SugarMonitor™ if this really enhances cognitive performance. How to prevent such use? Or is this the wrong question, and is it perfectly acceptable that employers ask their employees to give their (enhanced) best?

Perplexed by the wide range of issues emerging in the debate, the government in 2021 asks the Council of Public Health and Care (in Dutch: RVZ) for advice on the best regulation of experiments with human beings, medical and non-medical.

One regime for all experiments with human beings

Today the Council of Public Health and Care published a report stating that one legal regime for all kinds of experiments involving human subjects is desirable. The Council was asked to reflect on this issue by the government, because an increasing number of new technologies can be used for both medical and non-medical purposes. The Council now suggests differentiating experiments with technologies involving the body by the extent of risk (for example because of the materials used, or the extent of invasiveness), instead of by the stated goal. This means that much more technologies will have to be subjected to judgment by ethical committees. To this aim, the committees should include members with different backgrounds and expertise.
NRC Handelsblad, October 22, 2023

Phase 4: Theranostics (2024 – 2030)

This final section once again imagines how further technological developments may give rise to controversy (step 2), this time focusing on questions of identity and the good life – so called ‘life ethical’ issues. New technological developments in molecular medicine appear to make human action and responsibility superfluous, thus changing what it means to be human. Moreover, personalized medicine might produce a society in which all bodies are constantly being monitored and subjected to experimental intervention. Both effects on human life and society meet resistance. The closure constructed here (step 3) implies that the new technology is not prohibited; it is left to the individual’s choice whether or not s/he wants to use it. This imitates a pattern that is clearly visible in many debates on new technologies encountering life ethical objections, as in the preceding phase, however, the ethical monitoring of technology is also extended.

In the wake of the advent of bodily monitoring systems, ‘theranostics’ (the combination of diagnostic and therapeutic technology) becomes a growing concern of medical R&D. Companies develop systems in which molecular monitoring devices (preferably wet sensors) are upgraded with a drug delivery function. Such ‘theranostic systems’ are promoted as the ultimate form of personalized medicine. If bodily functions are continuously measured, deviations can be diagnosed on the basis of personal function charts. In addition, the type and amount of a drug, as well as the right timing of its release can be determined on the basis of personal values. Finally, the effectiveness of the drug will be closely monitored, so that the dose or even the release itself can be continuously adapted to your body’s response. In this way, both under- and overdosing of drugs, can be avoided.

The individualization aimed for in theranostics is widely acknowledged as a valuable ideal. It fits well with the trend towards individualization that has been visible in Western societies since at least World War II. Moreover, this type of technology links up with non-medical technologies aimed at improving comfort and reducing the burden of human action and responsibility, like the fridge that keeps stock of your supplies and warns you if you are almost out of milk or juice. Theranostics supplies one with drugs one cannot forget to take. In commercial publications, it is presented as more reliable than human beings themselves.

However, the individualization made possible by biomedical technology also creates methodological and ethical problems in experimental research. As an epidemiologist and a moral philosopher in 2025 argue, the personalization of health care makes this care in general more experimental. The aim of personalization leads by definition to differentiation, if not to a complete fracturing of research populations. In the past, some argued that researchers should be obliged to ensure that all relevant populations, especially the weaker ones, are included in their experimental set up. By now, the authors argue, this demand for representation is not a viable strategy anymore (if it ever was), since it would mean that every potential user should be included in experiments. Personalized medicine erases the boundary between experimental and regular care anyway: each time an existing drug or device is applied to someone new (with potentially unique characteristics) the application is in a way experimental.

Some interpret this argument as a plea to extend the rules for experimental (medical) technology to regular care. Others argue just the opposite: if experiment is the rule, instead of the exception, why have separate rules and procedures for it? Perhaps society should focus on the major risks and uncertainties, instead of squandering limited time and budget on the ubiquitous minor ones.

A Dutch sociologist publishes a newspaper article in which he puts the discussion on theranostics in a broader perspective. In his view, the trend towards a 'safety society' has by now been developing for almost half a century. Citizens perceive themselves as vulnerable and if they experience some kind of adverse event, they consider themselves victims. They hold the state accountable to protect citizens against such events; alternative ways of organising protection are neglected. The sociologist ends his article by arguing that a radical change of perspective is needed. Instead of claiming the right to be protected, citizens should learn how to deal with misfortune and cultivate the virtue of resilience. As for personalised medicine: we should acknowledge its experimental character, and start thinking of how to deal with adversity in experimenting.

Some groups of health care professionals fear that theranostics will have a negative impact on our bodily experience and our view of health:

Research on theranostics should be banned

Research on theranostics (combined diagnostics and therapeutics) should be banned, says the Dutch Association of Anthroposophist Physicians (NVAA). The association today publishes a report in which it argues that this type of research is highly problematic. First, theranostic systems make human judgment whether or not to intervene superfluous. As such, they limit not only the role of medical professionals, but also the room for patients' input. More fundamentally, theranostic systems suggest that an individual's own bodily experience is not relevant anymore: the system decides when and how intervention is necessary without taking into account whether there are any complaints. Finally, these systems suggest that only chemical intervention may counter the process, neglecting the importance of changes in lifestyle or environment. These systems, that is, stimulate unnatural solutions to bodily problems.

From: *Press release NVAA, Zeist, September 2026*

However, producers of theranostics counter that (1) no one is forced to use theranostic systems and (2) potential users should of course be informed about the promises and risks involved, as well as alternatives. This is exactly why these systems are not offered on the market, but can only be prescribed by medical professionals. They stress that it is misleading to characterise theranostics as 'unnatural'; these systems try to restore a body's normal functioning by identifying and remedying a shortage or surplus of specific bodily substances. The chemical substances administered are often identical to those produced by 'normal bodies'. Moreover, because of the personalization of dosage, location and moment of release, body parts that function well will not be affected by the intervention, as is the case in lifestyle interventions. Both the goal and the methods of theranostics, therefore, take the natural functioning of a healthy body as their model. The accusation that theranostics is unnatural because it uses chemical substances, amounts to denying that bodily processes are chemical in nature by definition.

The anthroposophist position is a marginal one, and the plea for prohibition is rejected by most participants in the debates as a form of unrealistic Luddism. There remains some political concern, however, over the blurring of the boundary between experimental research and regular care. As a result, the Minister of Health decides to refer experiments with theranostics for the time being to the Central Medical-ethical Review Board (CCMO). In addition the Health Council (GR) and the Council for Health Research (RGO) are asked to prepare a joined report on the shifting boundary between experimental research and medical care.

The report is published in 2027. It states that there is indeed a non-negligible risk in personalised medicine like theranostics, even after it has been tried on a large group of experimental subjects. However, if research populations are carefully composed, experiments with a limited number of subjects should be able to indicate the most important risks. Therefore the two councils think it still makes sense to separate research from regular use. Nonetheless, they propose to alter existing regulations in two ways. First, a protocol should be developed for the composition of research populations. Researchers should ensure that new theranostics are tried on sufficiently diverse subjects. If risks appear to be acceptable in the experimental stage, the theranostic device should be allowed on the market for the time being. However, since positive results in the research stage do not guarantee that the device will be safe for everyone, continued monitoring after introduction is deemed advisable. The councils suggest that all physicians prescribing theranostic devices should be obliged to report adverse effects to a central monitoring system. The data in this system will be continuously analysed and if clear patterns in adverse effects occur, the license of a device should be adjusted or even withdrawn completely.

In a commentary in the Dutch Newsletter for Bio-ethics, a philosopher of technology argues that this proposal gives monitoring devices a taste of their own medicine. Since technological development has extended the possibilities for monitoring of bodily functions, technologies themselves as well as their developers also have become subjected to much more extensive monitoring. In a more serious vein, she points out how this development illustrates the force of arguments from precedent. Apparently those were right who predicted that monitoring specific activities and domains would lead to ever more monitoring activity. If the Minister puts the councils' suggestions into effect, the observing gaze will finally permeate society at all levels.

Conclusion: The Merits and Limits of Techno-Ethical Scenarios

The preceding scenario fragments show that it is possible to imagine in a systematic, concrete and plausible way how the interaction between technology and morality might lead to moral controversy, how such controversies might be 'solved' and how technology and morality might co-evolve. The fragments do not constitute a complete narrative of the potential interactive evolution of technology and morality in this specific domain. It will be clear, nonetheless, that society in twenty years from now might end up with a technological *and* a moral landscape that is significantly different from the one we know now.

Of course the scenario sketched has its limitations. As will be clear from the description of our method, the content of this scenario is largely researcher/expert based. Input by experts from the field of bionanotechnology, as

well as by different types of stakeholders, would definitely have broadened the scope of the scenario. The participation of a broader set of stakeholders might also help to check the plausibility of the scenario. We involved a limited number of participants only because of time constraints, but the framework we propose in principle does allow for such a broader input. The same is true for the limitation of the number of scenarios. Whereas we developed only one scenario, our framework definitely enables the construction of different variants or even opposing scenarios. It is clear that such a plurality of techno-ethical scenarios would even more enhance the ethical imagination. It might also prevent misinterpretation of these scenarios as making predictive claims

Notwithstanding these obvious limitations, the scenario presented here does constitute a ‘proof of principle’. It shows that our framework enables the construction of scenarios that capture the dynamic and mutual interaction of technology and morality. Such techno-ethical scenarios are valuable tools to exercise one’s imagination of the potential impact of emerging technologies on morality, and vice versa. This reflection is currently lacking: technology assessment largely focuses on hard impacts, like risks for health, environment, and safety. Our framework thus is a valuable addition to the TA-toolbox.

Our framework was developed first and foremost to help policy makers to anticipate ethical controversies regarding emerging technologies. But it can also be used in the context of public debates with a variety of participants, to broaden the scope of such debates. Actually, the framework is currently being used for both groups. The framework of NEST-ethics has been made available to Dutch policy makers in the form of a brief, accessible, report (Swierstra 2009), which resulted in a workshop to train them in using this framework. Furthermore, we currently use the framework to develop brief vignettes and scenarios exploring potential ‘soft’ impacts of nanotechnology. These vignettes and scenarios are used in the Dutch public debate on nanotechnology that is organized in 2010 (www.nanopodium.nl).

Whether used by policy makers, by organizers of public debates, or both, techno-ethical scenarios can contribute to more inclusive deliberation on the impact of emerging technologies in two ways. First with regard to the *content* of the debate: it helps to set a more inclusive agenda and thus broaden the type of issues, arguments and controversies that may be put forward. Secondly, techno-ethical scenarios contribute to a more inclusive *process* of deliberation, stimulating public debate on these issues at a stage when developments have not yet progressed beyond the point of no return. Techno-ethical scenarios allow all stakeholders to be taken into account and/or to have active input in the decision making process, thus enhancing the democratic quality of this process.

Finally, techno-ethical scenarios enhance the *reflexive character* of ethical debate and decision-making. By showing how moral change might come about, a

reflexive distance is created towards current as well as potential future morality. Such scenarios warn us that current moral norms cannot be automatically supposed to be valid criteria to judge the desirability of future developments. In addition, they show that moral change usually is gradual and slow instead of radical and sudden. Thus, the implicit ‘moral presentism’ or ‘futurism’ that is often implicit in other scenarios can be avoided.

This may seem to produce complete uncertainty as to which norms can be thought of as legitimate criteria, or even to lead to relativism: if no moral norm is exempt from potential change, it might not be possible to rationally decide which one is best. We think this is too pessimistic. Techno-ethical scenarios help to multiply perspectives from which to judge current and future developments. As such, they will probably lead to more debate and controversy at first. Indeed, they are not written to indicate which closure would be legitimate or desirable. However, multiplying perspectives is functional: it opens up for explicit, early and democratic consideration developments that previously more or less happened to us. Techno-ethical scenarios enable us to decide whether or not to hold on to our current morality in view of potential futures.

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