Centre for Ethics and Health of the Netherlands

List and summaries of CEG reports

For all well-considered health policy

The Netherlands Centre for Ethics and Health (CEG) identifies and informs about developments in the field of health which deserve a place on the government’s ethical policy agenda.

The CEG is a joint venture of the Health Council of the Netherlands and the Council for Public Health and Health Care.
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Centre for Ethics and Health of the Netherlands: for a well-considered health policy

Two collaborating advisory councils
At the instigation of the former minister of Health, Welfare and Sport, Els Borst, the CEG was founded in 2003 as a joint venture of the Health Council of the Netherlands (www.gr.nl) and the Council for Public Health and Health Care (www.rvz.net). To carry out its function properly, the CEG maintains innumerable contacts. The national and international networks of the Health Council and the Council for Public Health and Health Care (RVZ) enable it to track social and medical developments and to focus on the important ethical issues.

The importance of ethics
When talking about our health, we all agree that it must be good. In the care for our health new options become increasingly available. But what should we do from an ethical point of view? Should we allow everything that can be medically and technically done? Those questions have no simple answer in a world full of different people, changing values and rapid developments. Again and again we have to determine what makes us better - literally, as well as figuratively. After all, our values affect our choices - as a patient, as a care provider, as a society.

Therefore, the Centre for ethics and health (CEG) is identifying current moral dilemmas in the broad field of health and health care. As policymakers, citizens and professionals, we sometimes encounter difficult moral issues. The CEG clarifies these issues and thus helps with making important, sometimes irreversible choices.

Think tank for responsible policy
The most important target group is the government, in particular the minister of Health, Welfare and Sport. Monitoring reports draw the government's and parliament's attention to moral dilemmas of our age and explore solutions. Thus, the CEG contributes to a well-considered, ethically responsible health policy, aiming at good care for everyone.

Knowledge bank and meeting point: www.ceg.nl
The CEG serves the government but is also a knowledge centre for a wider public. The website plays a pivotal role in this. On www.ceg.nl you can download the monitoring reports and you can see what the CEG is currently working on. Most of the reports and their summaries are available in English. The digital newsletter (in Dutch) keeps subscribers informed about the activities.

In addition (also in Dutch), there is a wealth of information available about a wide range of ethical themes. Links to essential websites on ethics and health enable you to explore particular topics further. For example, the website refers to relevant legislation and literature. An agenda informs visitors about congresses, symposia and courses. Visitors can also respond and debate. Furthermore, there is a digital reporting centre to draw attention to moral dilemmas from health care practice.
Overview Ethics and Health Monitoring Reports

Summaries or complete reports are available in English:
See also our English version of the website www.ceg.nl; you can download the monitoring reports and see what the CEG is currently working on.

2014
- Shared decision-making. A cluster of interviews about experiences (English summary not available)
- Lifestyle influencing: between paternalism and neglect (summary)

2013
- Shared decision-making by professionals and patients. Normative background (English summary not available)
- Lifestyle differentiation in health insurance. A survey of ethical arguments (summary)

2012
- Forward Look: Ethics and Health (complete report)
- Health policy in consideration of good care for animals and environment (complete report)

2010
- The ‘thousand-dollar genome’: an ethical exploration (complete report)
- So far away and yet so near?

2009
- Dilemmas of nurses and carers (summary)
- He who pays the piper calls the tune? On funding and the development of medical knowledge (complete report)
- Ethical considerations in healthcare-related TV Programmes (summary)
- Care for the unborn child. Ethical and legal aspects of fetal therapy (complete report)

2008
- Dilemmas on the doorstep. Reading early warning signs and intervention by professionals in parenting situations (summary)
- Farewell to non-commitment. Decision systems for organ donation from an ethical viewpoint (complete report)

2007
- Appropriate evidence. Ethical questions concerning the use of evidence in health care policy (complete report)
- Financial stimulation of organ donors (complete report)
- Considerations pertaining to neonatal life termination (complete report)
- Formalization of informal care (no English summary not available)

2006
- Confidence in responsible care? The effects of performance indicators and moral issues associated with their use (complete report)
- Should blood donors be tested for Variant Creutzfeldt-Jacob disease? (complete report)
2005
- Embryonic stem cells without moral pain? (complete report)
- Ethical aspects of cost-utility analysis (summary)
- Now with extra bacterial Food products with health claims (summary)
- Tracking down threats to health: screening in GP practice (summary)
- Health care professional and police informant? (summary)
- Ethics in health-care institutions and in the education of care professionals (summary)

2004
- Fertility insurance: medical and non-medical reasons
- Terminal sedation (complete report)
- Pesticides, cosmetics, paints: the protection of test subjects in exposure studies
- Advanced homecare technology: moral questions concerning an ethical ideal (complete report)
- Advanced homecare technology: moral questions concerning a new healthcare practice (complete report)
- Informal care, cost control and personal responsibility
- Economisation of health care and professional ethics (complete report)

2003
- Demanding behaviour and aggression from care clients
- Coercion and informal pressure in healthcare
- Cultural identity and self-determination for care clients of ethnic minority groups
- Self-determination and individual responsibility of people with mental handicaps
- Activities with gametes and embryos
- Screening of neonates for congenital metabolic disease
- Medicines for children
- Human enhancement

Forthcoming publications 2014 Ethics and Health Monitoring Report, CEG
- Inter-professional ethics in care
- Integrity in healthcare organizations
- Wish-fulfilling medicine
Summaries Ethics and Health Monitoring Reports 2006-2014
Lifestyle influencing: between paternalism and neglect

This report charts the arguments used in the public debate over lifestyle influencing and paternalism, the different positions in this debate and the pros and cons of lifestyle influencing.

The report describes six situations that have recently led to social debate on limits to lifestyle influencing by the government, health insurers and employers. The discussions concerned a so-called ‘fat tax’, the placing into care of a child that is given raw food only, the ban on smoking in small catering establishments, employer policy on lifestyle, the decision of the Health Minister to remove courses promoting a healthy lifestyle from basic health insurance and the proposal to make bicycle helmets obligatory in order to reduce injuries.

The report goes on to distinguish three positions in the debate on limits to lifestyle influencing:
(a) ‘Lifestyle influencing is always acceptable when it leads to health benefits.’
(b) ‘Lifestyle influencing is always unacceptable because it interferes with individual freedom.’
(c) ‘Even when lifestyle influencing leads to health benefits, it is only acceptable under certain conditions.’

Position (a) is too simple. Lifestyle interventions always involve financial and moral costs (e.g. loss of individual freedom) and therefore always require justification.

Position (b) is also too simple, because it excludes lifestyle influencing necessary to prevent harm to other people. The strength of position (b) lies in the observation that a measure promoting a healthy lifestyle is not by definition in the interest of all people. People have various interests existing side by side and if these clash and are weighed against each other, healthy living will not always take priority. The underlying idea is that choices regarding the good life are an individual freedom. The position that lifestyle influencing is unacceptable because it interferes with individual freedom is stronger if the measure radically encroaches on civil liberty (i.e. is coercive), if it is aimed at adults who are able to give informed consent and if it is implemented without prior consultation.

Position (c) is a broad-church position taken by most people in the Netherlands. Three possible justifications are discussed.

The first possible justification of lifestyle influencing is: ‘If the behaviour to be influenced harms third parties, it is acceptable to influence this behaviour.’ Thus most people accept that the harmful effects of passive smoking are a valid reason for banning smoking in some situations.
The second possible justification is: ‘If there are strong external factors that stimulate an unhealthy lifestyle, it may be acceptable to influence this lifestyle.’ Unhealthy behaviour is also influenced by factors beyond the individual’s power, like an unhealthy social environment, the influence of industry, addiction and lack of information. Unhealthy lifestyles are more frequent among people with a low socio-economic status. This argues for the need to strengthen the conditions for choosing a healthy lifestyle, for instance by boosting health skills and making the social environment healthier.

The third possible justification of lifestyle influencing is: ‘If autonomy or freedom is not seriously threatened, lifestyle influencing may be acceptable.’ Nowadays ‘nudging’ is a popular concept: certain choices are stimulated, but people can also opt out. Nudging deserves further investigation, both into potential positive effects and into potential ‘invisible’ crossing of ethical boundaries.

The report concludes with a set of questions instrumental to assessing whether lifestyle influencing is acceptable and advisable in the light of possible objections relating to paternalism:

- What are the expected positive effects of the measure and who benefits from it?
- Are there alternative measures that achieve the same goal with less influencing?
- Are third parties harmed by the behaviour to be influenced?
- What external factors stimulate an unhealthy lifestyle?
- Is autonomy or freedom seriously threatened by lifestyle influencing?
- Is influencing autonomy or freedom acceptable in the light of the possible justifications?

In this way the report aims to contribute to the work of policy-makers, employers, insurers and others who have to make choices in the many grey areas of the debate on lifestyle influencing and who in doing so have to take account of social views, political-philosophical considerations and scientific insights into lifestyle and health.

A complete report will soon be available:
See also our English version of the website www.ceg.nl: you can download the monitoring report and see what the CEG is currently working on.
Lifestyle differentiation in health insurance. A survey of ethical arguments

Should people who smoke, work too hard, don’t exercise enough, drink alcohol, have unsafe sex, eat too much, play injury-prone sports or have another unhealthy lifestyle pay more in terms of premium, policy excess or individual contributions for basic health insurance? And should people who don’t do these things be rewarded? The ethical debate on these questions is topical and emotive. The aim of this report is to structure and assess the ethically relevant arguments in the debate on financial differentiation according to lifestyle in basic health insurance.

The debate on whether lifestyle differentiation should be introduced in basic health insurance divides opinions on the following questions:

- Is lifestyle differentiation feasible?
- Should lifestyle differentiation be introduced for the sake of prevention?
- Does lifestyle differentiation lead to a fairer distribution of costs?
- Does lifestyle differentiation promote solidarity?

The first question concerns a precondition; the other three are about motives.

The first point of discussion is the feasibility of lifestyle differentiation. Though monitoring unhealthy behaviour is often impracticable, there are ways of implementing lifestyle differentiation. Further investigation will have to show whether this is permissible under European law. Implementation also raises ethical questions, e.g. about privacy and stigmatization.

The second point of discussion is whether prevention forms a convincing motive for lifestyle differentiation. It is uncertain whether lifestyle differentiation in basic health insurance has favourable effects on behavioural change and thus promotes health. Also, prevention as a motive for lifestyle differentiation raises questions about paternalism.

The third point of discussion is whether lifestyle differentiation leads to a fairer distribution of costs. Scientists disagree on whether certain unhealthy lifestyles are in fact more expensive than others. Views also differ on what is fair. On the principle ‘the polluter pays’ it seems fair to make people pay for the costs of their unhealthy life style. But this view is open to the objection of victim blaming: an unhealthy lifestyle is determined by external factors too, such as socio-economic status and an unhealthy social environment. Alternative views of fairness hold that fairness does not require that everybody gets the same results, but that everybody has sufficient freedom to pursue individual goals, such as a healthy lifestyle.

The fourth discussion point is whether lifestyle differentiation promotes solidarity. It is confusing to talk about ‘solidarity’, because different meanings are attributed to the concept. It is useful to draw a
distinction between solidarity as actual behaviour and solidarity as attitude and between affective solidarity and calculating solidarity. The proposition that lifestyle differentiation makes citizens more willing to help pay for a system of solidarity (solidarity as attitude) is an empirical claim which is difficult to verify and necessarily speculative. If ‘recognition’ is a crucial factor in disposing people towards solidarity, lifestyle differentiation might undermine their willingness by emphasizing the differences between people.

The debate on lifestyle differentiation is likely to continue for some time. We hope that this report will help to clarify the main ethical arguments, so that the debate can move forward.

A complete report will soon be available:
See also our English version of the website www.ceg.nl; you can download the monitoring report and see what the CEG is currently working on.
The ‘thousand-dollar genome’: an ethical exploration

Sequencing an individual’s complete genome is expected to be possible for a relatively low sum (‘one thousand dollars’) within a few years. Sequencing is determining the order of base pairs that make up the genome. The result is a library of three billion letter combinations. Cheap whole genome sequencing is of greatest importance to medical scientific research. Comparing individual complete genomes will lead to a better understanding of the contribution genetic variation makes to health and disease. As knowledge increases, the ‘thousand-dollar genome’ will also become increasingly important to healthcare. The applications that come within reach raise a number of ethical questions. This monitoring report addresses the issue.

Analysing the entire human genome
Whole genome sequencing (WGS) can lead to whole genome analysis (WGA), in which the meaning of the raw data obtained during sequencing is fleshed out. This is done using software integrating the latest scientific insights into the relationship between genes and health. Filters may be used to selectively examine certain parts of the genome (targeted analysis), for example when diagnosing diseases with a known genetic substrate. Use of filters helps limit the amount of non-relevant information. Using this approach, WGS-based diagnostic testing yields results that are not different from diagnostic testing with existing methods, such as DNA chips. If WGS becomes cheap enough in future, it will likely become the standard approach.

Genome-wide diagnostic testing
WGA (complete sequence analysis) is also expected to play a role in healthcare, specifically the diagnosis of diseases for which the genetic background is not yet (or insufficiently) clear. Searching the entire genome will often allow a diagnosis to be made. This approach was recently already implemented, but using less powerful techniques. Genome-wide diagnostic testing inevitably means that far more genetic information about the patient is revealed than is necessary for answering the help demand. Among other things, this raises questions about the feasibility of informed consent, the possibility to shape the ‘right not to know’ and the limits to the requirement to inform patients. What should happen with the (raw) sequencing data afterwards? Should it be stored? Is it allowed to be destroyed? What about the analysis findings (genetic information): should all unsought for findings also be saved? What about The ‘thousand-dollar genome’: an ethical exploration genetic information not desired by the patient, and therefore not supplied to him or her? Finally: can a doctor be expected to actively inform the patient if new scientific knowledge means past that data obtained from past whole genome analysis may be viewed in a new light?

Genome-wide screening
Some commentators expect full genome sequencing and analysis for every individual will be worthwhile in a few years. This would be performed without a concrete medical indication, meaning it is screening rather than diagnostic testing. Whole genome screening creates a personal genomic database (‘personal
genome’) that can subsequently be used to deliver ‘personalised medicine’ to individual patients. While the first steps in this direction have already been taken (particularly in the field of pharmacogenetics: ‘personalised medication’), this largely remains something for the future. According to some, analysing the personal genome would ideally be done when people reach legal age. The individual can then decide for himself whether or not to take part in this form of screening, and it is still early enough in life to benefit sufficiently. The usefulness may consist of lifestyle advice, treatment and prevention tailored to the personal health profile, but also of risk information that could affect reproductive decisions. In addition to the (currently largely hypothetical) advantages of analysing the personal genome, there are also all too real disadvantages to obtaining information that could be a burden or even harmful. Disadvantages include worry caused by (still) unclear findings and the resulting – often unnecessary – contacts with healthcare. As long as there is no clear positive balance of advantages and disadvantages, there can be no responsible implementation of whole genome population screening within public healthcare. However, as soon as WGS/WGA becomes cheap enough, commercial parties will likely see a market. Whole genome tests are already commercially available, albeit currently only implementing methods that only examine small, common variations in the genome. The existing commercial availability of preconception testing for recessive genetic conditions to individuals and couples who wish to have children is also a potential area for expansion. Application of WGS in this context can easily lead to the question of why analysis should be limited to finding out about carrier risk status. If removing filters is enough to obtain a whole genome analysis, the question is not longer what we do, but what we do not want to know about ourselves.

**Genome-wide screening of newborns**

Some advocates of the concept of tailor-made medicine suggest that analysing personal genomes is best done as early as possible in life, namely at birth. Practically, this would entail expanding the current neonatal heel prick screening based on WGS/WGA. Questions other than those already listed regarding the balance between advantages and disadvantages arise. The question is also whether analysing the complete genome of a child without a medical indication is acceptable, given all kinds of information about genetic characteristics will become known that is only important far later in life. Don’t children have the right to decide whether or not they wish to know about the strengths and weaknesses in their own genome later in life? Current heel prick screening does not face this problem; it focuses solely on conditions where timely treatment or prevention (often a diet) can prevent significant health harm to the child. However, there is already a trend towards expanding neonatal screening. According to the American President’s Council on Bioethics, the underlying interests – particularly those of scientific research – are so great that the scenario of genome-wide screening of newborns will be difficult to prevent.

**Genome-wide prenatal diagnostic testing and screening**

It is now no longer a fantasy that the full genome could be sequenced even earlier in life, namely during pregnancy. This would not be done in the interests of personalized medicine, but within the context of prenatal testing focused on allowing informed decisions about whether or not to carry the pregnancy to term. If this is done based on a possible health problem in the foetus, it is referred to as prenatal diagnostic testing; a routine offering is referred to as prenatal screening. Genome-wide diagnostic testing is already being used (using current techniques) to help clarify unexplained ultrasound findings. However, the scope of prenatal screening is also expected to be broadened. Eventually, those who want as much information as possible about the foetus will no longer be happy with anything less than the complete genome. The question arises of whether the primary goal of prenatal screening will not be threatened. The broader the test, the more diverse the potential outcomes, the more difficult it will be to enable the pregnant woman (and her partner) to provide true informed consent. Will this not lead to almost every pregnancy delivering a finding that forces the pregnant woman to decide on whether or not to abort, even if only because of a finding whose meaning is not yet clear? Finally, this scenario creates a new and currently unaddressed
problem: children born after whole genome diagnostic testing or screening already have a fully analysed genome. The question remains whether or not this harms the right of the future child to decide for him or herself.

**Genome-wide screening of embryos**

The introduction of increasingly broad testing also applies to the screening of embryos created for an IVF treatment (pre-implantation genetic screening, PGS). This involves the selection of embryos that qualify for implantation into the uterus. Currently, this is conducted largely based on morphological characteristics that appear to be important for a chance at a successful implantation and pregnancy. More informative tests that look at chromosomal abnormalities are currently being developed. Certain experts believe that it will eventually be possible to conduct genome-wide analysis on IVF embryos. This seems to shift the goal of screening from selecting the embryo which has the best chance of growing into a child, to selecting an embryo that will grow into a child that is as good, or at least as healthy as possible. If a choice must be made, is it not the responsibility of doctors (and future parents) to choose the embryo with the best health prospects? However, it would also mean that the 10

**Existing review frameworks under pressure**

The questions raised by the potential implementation of the thousand-dollar genome are not all new. The scale of the challenges is, however. More important is what is happening with the normative frameworks normally used to thematise and answer such questions. They are under pressure, starting to overlap or run into each other. This applies primarily to the difference between diagnostic testing and screening. If whole genome sequence analysis is used to determine the genetic background of a poorly understood health problem in an individual patient, the motive remains diagnostic testing. However, given the fact that at most a tiny amount of all health information this delivers will have anything to do with the specific problem being investigated, the procedure also closely resembles a form of (undirected) screening. If this is the case, should such research not be reviewed using the normative framework developed for screening?

A second issue is how analysing personal genomes without a medical indication relates to the normative framework developed for screening. Because it is impossible to grasp what predictive information genome-wide, undirected screening may yield, it is impossible to determine what the balance of advantages and disadvantages for the individuals to be tested will be. In the context of the normative framework, it would appear not to be a good idea. But does that framework provide the correct perspective for reviewing the analysis of a personal genome? Reasoning from the ideal of personalised medicine, everyone is a patient from cradle to grave. The distinction between screening and patient care then loses all meaning. Or maybe analysing the personal genome is an issue of the right of individuals to obtain genetic information relating to themselves? The discussion on this subject will inevitably receive a fresh impulse if a market for sequencing and analysing personal genomes develops. The distinction between reproductive and non-reproductive screening is also becoming blurred. Until now, these were separate worlds with their own normative frameworks and principles. For non-reproductive screening, the emphasis is on health gains and a certain amount of directiveness is not seen as problematic: it is fine to draw people’s attention to their responsibility for their own health. Reproductive screening, on the other hand, traditionally has a strong focus on the highly personal character of reproductive decisions with an ideal of professional non-directiveness. The application of genome-wide tests would lead to a blurring of the borders between these two worlds, leading to difficulties determining which normative principles should guide decision-making.

In conclusion, familiar normative frameworks appear to lose at least part of their organizing capacity and guiding character. Although some of the developments discussed are problematic when viewed from within these frameworks, there is also room to ask whether review or recalibration of these frameworks is
necessary, should we wish to continue providing guidance for the application of scientific knowledge in healthcare.

Debate and new guidelines required
Further reflection on the developments outlined above and the normative implications thereof for all parties involved, including clinicians, scientists, jurists, ethicists, patient organizations and policy makers is of great importance. To begin with, there is a need for guideline development by the professions involved in the application of genome-wide diagnostic testing in adults, children and foetuses. The most current question is how to responsibly deal with unsought for findings of such diagnostic testing. Given the complexity of the matter, in both normative and scientific terms, there is also a need for more comprehensive reflection and debate.

A complete report is also available:
See also our English version of the website www.ceg.nl; you can download the monitoring report and see what the CEG is currently working on.
So far away and yet so near?

Care at a distance, also known as ‘telecare’, is a social promise. For example, technology makes it possible to use a compact touch-screen to monitor important physical functions of patients or to provide people suffering from dementia with instructions on preparing food, without a care provider having to be physically present. Telecare could enhance care provided in the home and thereby improve it, make patients more self-reliant, strengthen informal care networks and, last but not least, it could provide a solution to the problem that demand for care is increasing at a time when the number of care professionals in the labour market is decreasing.

Most telecare is currently in the pilot stage and is still supplementary to existing care. This advisory report discusses the realistic scenario in which care at a distance will replace a considerable part of direct care in the home. Whether intentionally or otherwise, in such a case telecare will change care relationships. The relationships between patients, care professionals and informal carers will inevitably be different; informal carers and patients will carry out more medical/semi-medical activities, whereas care professionals will have more of a coaching role. The questions this advisory report poses are:

What ethical questions does care at a distance of this kind raise? Which parties should consider those ethical questions and how should they do so?

The advisory report explores the question in two ways: on the basis of a reference literature study and on the basis of a focus group study. In the focus groups, patients, informal carers and care professionals were asked for their opinions on telecare. This revealed a difference of opinion between younger and older patients. Younger patients feel resistance to telecare because they have no desire to be constantly confronted with their illness at home. They are also concerned about the privacy of their digital medical data. However, they do think that telecare could make care more accessible for them. Older patients in our study had less resistance to telecare, perhaps because they had integrated their illness more in their lives. The advantage they see of telecare is that it enables them to live at home independently for longer. All patients wanted to be able to determine the time of contact themselves; they do not wish to be constantly checked via a webcam, for example. The informal carers who were interviewed found it a pleasant experience to be able to contact the patient through telecare, as it reduced the frequency of visits they needed to make to check that everything was all right. They also thought it was reassuring that remote professional help was available. However, they were afraid that they would gradually be assigned more responsibilities. Various informal carers thought that care at a distance could never take the place of care provided in person. The spectre of an impersonal call centre was raised. Care professionals who are not yet working with telecare are more hesitant about it. Conversely, the interviewed care professionals who were already working with telecare thought that it made their profession more engaging. Examples they mentioned included that they could be in touch with a patient several times a day and that it was easier to
determine if a visit was necessary. They indicated that the screen-to-screen contact made the relationship more personal, rather than more impersonal. Care professionals also thought that telecare increased the privacy of patients and possibly that of other members of their household.

On the basis of the reference literature study and the focus groups, the advisory report provides various ethical points for agendas concerning the implementation of telecare.

**Personal contact** is part of proper care. However, telecare need not be an obstacle to personal contact; a webcam also offers face-to-face contact with the care provider and can even make care more personal. However, people want to see a trusted and familiar face on the screen. This therefore calls for a permanent telecare nurse instead of a call centre with changing care providers. Moreover, it would be advisable to acknowledge that some necessary types of direct care (wound care but also a comforting arm on a person's shoulder) cannot, in principle, be replaced by telecare.

Telecare can enhance patients’ options for **self-management**. Systematically updating their own medical records puts patients in a better position to look after themselves in their own way. However, this assumes that the patient is highly disciplined and meticulous.

Ethically speaking it is important for patients to be able to live the life they choose as far as possible. It is essential not to lose sight of patient **autonomy**. This assumes that the patient is able to consider values and is not automatically subordinated to a medical regime. Cooperation between professional and patient which attests to respect for the patient’s individual lifestyle is therefore also one of the criteria that has to be met by care at a distance.

There should be no **division between self-reliant and non-self-reliant** in care. If telecare involves the implicit assumption that users are media-literate and have a good social network, such a division will be reinforced. On the other hand, telecare can also be arranged so that it supports those who are non-self-reliant and makes them more self-reliant. The latter is preferable from the ethical point of view and it therefore warrants the attention of manufacturers and care professionals.

At first sight, implementing telecare appears to put pressure on a person's home life. After all, equipment is installed in the home. However, it turns out that patients tend not to feel their **privacy** is being infringed, provided they are able to decide for themselves whether or not they wish to cooperate in a given type of telecare and provided they are able to choose when professionals ‘observe them’ through a monitor.

However, telecare equipment in the home can lead to increasing medicalisation of private life; some patients would prefer to avoid this. There is also the question of what happens with all the personal measurement data exchanged via the internet. Here, too, it is advisable to actively seek forms of telecare that leave home life intact as far as possible and that keep as much space for freedom of action as possible.

An ethical point is whether users will in due course still be able to **choose** a form of telecare that they consider pleasant or at least acceptable. For example, with telecare an obvious step might appear to be that family and friends would take over some of the physical care. However, research shows that patients would rather be cared for by a professional than by family members and friends. This effect of telecare would therefore be counter to patients' wishes. Telecare can provide informal carers with support and ease their workload but it can also mean that informal carers find themselves being assigned more care tasks, care tasks which they have not ‘chosen’ but which they will not readily refuse out of a sense of duty. The freedom of choice of care professionals may also enter into the discussion. Will they still be able to
choose what they deem to be proper care, namely care in which the human dimension continues to be part of their work?

Implementing telecare also requires proper consideration of the division of *responsibility and liability*. It is advisable to guard against patients and informal carers gradually being assigned all kinds of medical/semi-medical responsibilities. It is important for care professionals and informal carers to have clarity about who is responsible for reading out the medical records that patients send. It is also important to clarify who is liable when mistakes are made if equipment malfunctions: the care institution, the user or the supplier?

Particular attention needs to be paid to the question of how to deal with patients suffering from dementia who in due course no longer remember that they *consented* to telecare, or those who consented to a form of telecare due to be replaced because the technology has been superseded.

Finally, it would be advisable to *monitor* the actual telecare, to see whether the care meets the ethical conditions. Healthcare providers can be expected to ensure that they treat the care recipient with respect and are mindful of what the social environment of patients is capable of providing. Guidelines on this can be drawn up in consultation with patient associations. Issues concerning privacy and liability should be regulated by legislation. This is a task for government.

**A complete report is also available:**

See also our English version of the website [www.ceg.nl](http://www.ceg.nl); you can download the monitoring report and see what the CEG is currently working on.
Dilemmas of nurses and carers (2009)

“I do think many people immediately think about things like euthanasia when ethics is mentioned”, says a carer working in home care. “But how we treat clients is also about ethics. You run into moral dilemmas every day if you look at it that way. The question is whether nurses and carers recognise these dilemmas.”

Moral dilemmas in daily care
Ethics, nursing and caring are inseparably linked. Unsurprising, as providing good care is, at its core, a moral practice. The essence is doing well, not harming, acting respectfully and not discriminating between people. Nurses and carers want to provide good care. They want to give patients and clients the care they need, and want to distribute care in a fair way. That is their moral ideal of care. Providing care is impossible without facing moral dilemmas, as it is not always clear what the right or best choice is. Like the carer quoted above states: nurses and carers regularly come face to face with moral dilemmas as part of their work: dilemmas that address both traditional ethical issues, such as euthanasia, and everyday caring activities.

Moral distress through changes in healthcare
In recent years, nurses and carers have been increasingly confronted with (moral) dilemmas, dilemmas caused by recent changes in the healthcare system, such as new legislation, new financial structures, greater public accountability and tasks shifting between care providers. These dilemmas are best described as moral distress; you know what good care is, but you feel powerless, hampered or unable to put this care into practice. This powerlessness to do good causes people to experience moral dilemmas.

These ‘moral dilemmas’ are different from (traditional) moral dilemmas that address the question: ‘what is good care in this situation?’. These dilemmas are more strongly related to the question: ‘how do I enable good care in this situation?’ It are additional tasks and requirements that lead to these types of dilemmas. Consider institutional requirements, such as achieving targets, meeting performance requirements and dealing with new financial structures, such as ZZPs (care severity packages) and DBCs (diagnosis-treatment combinations). These changes make nurses and carers feel overwhelmed by additional tasks, which take time away from providing good care.

Changes that most affect nurses and carers

GOOD CARE FOR MINOR INDICATIONS
The indicated care remotely determined by the independent CIZ (Dutch centre of eligibility for care) employee frequently does not meet the care requirements. Carers and nurses are frequently faced with this situation: they know the patient, client or resident well, they see what care is required, but

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1 Carer statement during CEG inventory round, May 2009.
cannot provide it fully. Unsurprisingly, nurses and carers say this is their most pressing concern. They are regularly faced with the dilemma of what to do: act on their own professional standards for quality care, or only provide indicated care?

LOYALTY RELATED TO UNDERSTAFFING
Second and third place are held by dilemmas associated with understaffing in healthcare: a lack of financial means, lack of personnel, understaffing and subsequent frequent use of poorly qualified personnel. Appeals are also often made to care provider loyalty. A third of the interviewed care providers indicate that they deal with this on a weekly basis. They are asked to work overtime due to understaffing. 42% are troubled by this problem. Being asked to come to work on a day off is another issue carers and nurses (49%) find difficult to cope with. These are the dilemmas that should be addressed first.

DIFFERENT DILEMMAS IN DIFFERENT CARE SECTORS
Both the Centre for Ethics and Health (CEG) and the Netherlands Institute for Healthcare Research (NIVEL) made an inventory of the dilemmas associated with recent changes in healthcare in three sectors – hospital care, care in nursing homes, and home care. There is common ground, but there are also a number of differences. Specific dilemmas faced in hospitals include differing views between nurses and doctors on patient treatment, diagnostic testing and hospital discharge. Nursing and care homes, on the other hand, are most concerned about care indications: getting the required care organised, even if it does not correspond to the care indicated by CIZ. This leads to dilemmas like: ‘can I give a client a little less time than indicated, so I can spend that time on another client?’ and ‘may I have a client request more care than required in order to obtain the right care indication?’ The underlying question remains: ‘How can I provide good care in this situation?’

Sources of moral distress
Moral distress consists of feelings of powerlessness, subordination and inefficiency, but also leads to passivity and blunted moral sensitivity. These feelings were frequently mentioned when we asked about daily moral dilemmas during both the CEG meetings and the NIVEL postal survey. They are caused by increased external pressure that appears impossible to resist. Carers and nursing staff feel overwhelmed by changes in healthcare that do not visibly improve the quality of care. ‘Cutting costs’ seems to them to be the only motivation. This conflicts with the motives that carers and nurses have for entering the field, and erodes their intrinsic motivation. It also leads to unacceptable deterioration and fracturing of care, a low trust social environment, and an inevitable draining away of more qualified personnel and influx of (too) poorly qualified workers. The deterioration of healthcare becomes a very personal issue, and leads to a general sense of moral unease and a lack of motivation.

Moral issues are not recognised, poorly addressed and not discussed
In daily practice, moral issues are often ignored, and neither identified or discussed. What was learned in nursing school is quickly forgotten in practice. Dealing with moral issues is not solely a personal issue (‘me and my conscience’), but also a social one. If ethical issues are never discussed, a care provider needs to have strong convictions to raise them anyway. Carers and nurses are generally shy in this respect. A sense of having reached the limits of acceptable care could also lead to a great moral debate. The lack of such a debate appears to be caused by a lack of professional self-respect. This creates a vicious cycle: lacking appreciation leads to care impoverishment and a hollowing out of the profession, which leads to low self-respect, which in turn leads to more lack of appreciation. And lack of appreciation in turn contributes to staffing shortages.
Solutions and good practices
Since many of these problems are not new, and are widespread, solutions are being sought and a number of initiatives have been developed. Some of the issues are related to the way healthcare is organised, and a shift in this area has been noticed. For example, the announced changes to the way in which certain Exceptional Medical Expenses Act (AWBZ) care indications are determined, returning part of the responsibility to the care provider. Other problems are caused by the fact that, due to a lack of time and funding people do not have the opportunity to 'deal with ethics', despite the clear desire to do so. However, initiatives including moral discussions, medical ethics meetings or organisational structures that leave room for everyday moral issues have been launched. Some have also pointed out that nurse and carer attitudes need to change as well. They will need to expand their professionalism, and stand up for the responsible and necessary care they believe in.

Giving and taking professional space
In order to prevent or diminish dilemmas and moral distress, nurses and carers need to take a stronger position. This requires efforts from their environment, but above all from themselves. It is a give-and-take situation: nurses and carers need to be given the space to take responsibility and use their professional insights. They know the resident/client/patient better than anyone else involved in the care process, and know exactly what care is required. On the other hand, they also need to ‘take’ the required space: nurses and carers can demand this room to act, position themselves more proactively, and not allow themselves to be pushed out of their professional role by systems or external demands.

The government can – and recently has begun to – ensure through policy initiatives that nurses and carers are given more space to take professional responsibility and provide care as they see it. The training of nurses and carers can play a part by providing new forms of ethics education suitable for each specific functional level. Institutions need to be more fully aware of day-to-day dilemmas faced by front-line care providers, and accept the associated responsibilities. Interest groups and professional nursing and carer organisations are the linchpins in this process, and can represent the professional group at political and government levels. They can also support professionals with good practices. Managers need to be the first to pick up and address any dilemmas faced. They are (jointly) responsible for maintaining a healthy balance between quality care and corporate efficiency. Finally, nurses and carers will need to take up a strong, confident position and trust their professional insights when fighting for the quality care they so dearly want to give patients, clients and residents.
He who pays the piper calls the tune? On funding and the development of medical knowledge (2009)

This advisory report examines the influence of financiers (especially industrial financiers) on the development of medical knowledge, and the ethical questions to which this gives rise. This also especially involves deciding on which fields of knowledge need to be developed and the actual development of that knowledge through research. The words ‘sponsoring’ and ‘sponsor’ are used below to refer to research ‘funding’ and the ‘financier’. This advisory report is based on a background study commissioned by the Health Council of the Netherlands which was conducted by Professor R. Bal et al., as well as a study of reference literature and interviews with experts. The Health Council of the Netherlands’ Standing Committee on Medical Ethics and Health Law compiled this advisory report. It has been published under the aegis of the Centre for Ethics and Health (CEG), a partnership between the Health Council of the Netherlands and the Council for Public Health and Health Care. The Health Council of the Netherlands is responsible for the content.

**Agenda influences**
Chapter 1 emphasises that besides industrial sponsors, other parties, such as government and charitable funds, also finance research and therefore influence the research agenda. Particular interests and compromises may also play a role in government decision-making concerned with setting the agenda and priorities for research paid for with public funds (which public interest should be given priority?). The fact that charitable funds exist for some diseases and not for others may also lead to distortions in knowledge development. Issues of this kind are also worthy of attention but are only discussed briefly in this advisory report.

**Industrial sponsoring**
Chapter 2 explores the influence of industrial sponsoring on the composition of the research agenda. It is precisely in this initial stage of knowledge development that the prescriptive character clearly comes into focus. Industry especially tends to take an interest in subjects and develop fields of knowledge which can be expected to earn money within the foreseeable future. This is understandable, given that a business has to be profitable to ensure its continuity. The public health knowledge requirement mainly plays a role in the composition of the industrial research agenda where need coincides with commercial feasibility. Commercial feasibility and social importance are compatible but the development of biomedical knowledge would be unbalanced if knowledge development became excessively dependent on industrial research. This would also have adverse consequences for the quality of prevention and care.

The warning against lopsided knowledge development is substantiated by four case studies: drug research; research into diagnostic devices; nutritional research; public health research. Gaps in knowledge developed in these fields are delineated. Possible downsides of increased interrelatedness between industrial and clinical research are also pointed out. There is a risk that the size of the fees paid by industry
may carry some weight in the composition of the clinical research agenda and could thereby detract from the attention paid to the social benefit and quality. Possibilities and limitations of Public-Private Partnerships (PPPs) in which research projects are carried out jointly by the public and private sector are discussed. The PPP model is especially suitable for research that is likely to produce economically valorisable results in due course. The model is not a remedy for research for which the results are definitely not commercially marketable, such as research into collective public health interventions.

**Unbalanced growth in biomedical knowledge**

Chapter 3 summarises the main results of the four case studies. The fields of knowledge studied are subject to all the consequences of the crowding-out effect: in fields of knowledge in which product sales and making profit play little, if any, role, development lags behind that in economically valorisable fields of knowledge, even if society has a definite need for the knowledge concerned. The following factors play a role in this:

1. Industry tends not to conduct more research than is required for a new product's registration, as in the case of drugs and diagnostic devices;
2. Possibilities for patenting are limited in certain fields, as in the case of research into the effect of foods on health;
3. Demand for commercial products is sometimes too low in certain domains, such as public health.

These findings give rise to ethical questions, such as about the extent to which the crowding-out effect leads to imbalances or even unjustifiable choices and results concerning knowledge development, possible restrictions on free choice of research priorities, and the responsibility of government and other parties to make adjustments. This and similar questions would need to be discussed in greater detail.

In the process of knowledge development, the stage of conducting the research follows that of setting the agenda and priorities. International literature has shown that when a company funds research into one of its own products, the results are more favourable for the product concerned than the results of alternatively funded research concerning the same product. This distortion in favour of the sponsor's product is disturbing, also because it can harm trust in research. Explanations of why sponsored research significantly more often produces better results for the sponsor's product are found at three levels: comparisons using a placebo instead of an active drug; selective publication of research results that are favourable for the sponsor; and the selection of a favourable comparison, as when an inadequate dose of the other drug used in the comparison is administered.

The fact that reference literature revealed results favouring sponsors’ products also raises ethical questions. What implications do these results have for the conduct of the various actors, such as doctors/researchers and their institutions, science journals and their editorial staff, sponsors/manufacturers and government? The parties concerned will have to engage in debate about this.

**Suggested solutions**

To conclude, chapter four includes suggestions on how the identified problems could be tackled. The question always revolves around the contribution that the aforementioned actors can make to possible solutions. Government can direct some aspects but changes in the attitude of professionals and the role of industry are also important.

The potential research capacity and the number of available trial subjects/patients in biomedical research are limited. In view of the results of the case studies and the crowding-out effect, the concern is that the available capacity is not always used to generate the most urgently needed knowledge from the public health point of view. Consequently, the aforementioned actors should jointly reflect on their role and
responsibility in funding biomedical research and setting the agenda and priorities. Various options for the parties concerned to combat the crowding-out effect are discussed. The parties must be persuaded that seeding trials (which are sponsored trials with the sole object of getting doctors to prescribe a registered product) produce no new knowledge and cannot therefore be scientifically justified.

Distortions in research results in the case of industrial sponsoring can be combated by preventing any research project intended to find research results that are favourable for the sponsor. The parties concerned can also help with this in their own way. The necessary steps towards achieving this have been made in recent years. If an accepted alternative treatment is available, placebo-controlled trials should be further reduced; research results that are disappointing for the sponsor should also be published; the optimum dose must be administered of the drug with which the comparison is being made.

The main assurance against distortion of this kind is the researcher’s independence. Reducing conflicts of interest between the sponsor and the researcher reduces the need for the researcher to be ‘agreeable’ to the sponsor, which reduces the likelihood of bias in research results. Conflicts of interest may arise through personal reward, for example, or other forms of financial support, such as opportunities to attend congresses and payment of the associated costs. Doctors/researchers should adopt a more assertive and aloof and thereby more independent attitude towards sponsors. Another important development is that ongoing studies are increasingly being made public through trial registers, which have to report conflicts of interest and sponsoring.

**A complete report is also available:**

See also our English version of the website [www.ceg.nl](http://www.ceg.nl); you can download the monitoring report and see what the CEG is currently working on.
Ethical considerations in healthcare-related TV programmes (2009)

A healthy interest in illness?

It all began with a recording in a TV studio with doctors or patients discussing illness and healthcare. By now there is a whole range of TV programmes in which sickness and health play a central role. Informative programmes are keen to provide widespread coverage of health-related topics, often illustrated with examples from daily medical practice. But light entertainment programmes have also latched on to the subject of sickness and health. The youngest and most popular phenomenon is the reality programme in which doctors and patients are shown in their natural habitat: in the accident & emergency department, the operating theatre, or the GP making a house call.

Of course these developments did not just come about by themselves. Over recent decades the dividing line between the public and private domain has become increasingly vague: emotions are more and more often shown in public, and therefore also on television. Moreover, the commercialisation of television means that it is profitable to magnify these emotions, because emotion sells. It is hardly surprising then that programme makers view the healthcare sector as a source of exciting stories, where victims are saved by heroes, but where villains are lurking.

Care institutions, caregivers and patients alike have proved to be willing partners in this. For care institutions television can be a means towards improving their image and can give them an edge over their competitors. Caregivers like to be in the spotlight, or to act as an ambassador for their professional group or institution. And patients enjoy the attention they receive, or they may be asking for awareness and understanding of their illness. Acting together, patients can even become a force to be reckoned with. It has been found that patient associations have a financial interest in many of the TV programmes on sickness and health. And of course we mustn’t forget the viewers who tune in en masse to the healthcare programmes on the television.

So all parties would seem to have an interest in healthcare programmes on television. Yet we must ask ourselves if this interest is always healthy and if there are no harmful consequences which have thus far not come to light. The world of the television programme maker and the world of the healthcare sector operate at different levels. Programme makers want to make programmes that inform and entertain, and any combination of these is possible. Caregivers want to provide the best possible care for their patients. These are very different starting points, which in some cases can lead to moral conflict.

We can request television makers that they carry out their work in an ethically responsible manner. But we cannot do much more than appeal to their sense of morality: they are free to launch their ideas and to ask people to cooperate in the realisation of these ideas. Care institutions and
caregivers have a much more closely defined responsibility when it comes to their patients. They are not free to say yes to every request. What considerations should they make when they are approached to take part in a television programme?

**Does the programme help to properly inform the public?**

To start with they need to form an opinion regarding the value of the programme. If its sole purpose is to entertain, the care institution should say no. People within its walls are confronted with sickness and death and it is bad taste to use this for purposes of pure entertainment.

However, entertainment programmes can also contain serious useful information. How does this affect a decision of whether or not to participate? The smaller the informative component of the programme, the greater the chance of a clash between the principles of the programme makers and the caregivers. This is something that care institutions need to be aware of.

Reality TV may well be ‘authentic’, but this does not mean it is always realistic. Heroics and innocence are often the motor behind the story. Moreover, to maintain the viewers’ interest a certain amount of tension is built up. This gives a distorted picture of the situation which may eventually lead to flawed expectations regarding what the healthcare sector has to offer.

It is more logical to participate in an informative programme. Caregivers may feel that they have a responsibility to inform the public, and television offers an excellent stage for information and debate. But here also the boundaries between the different genres are not always clearly defined. Even an item for the news bulletin may be intended to amuse. And even if the main purpose is to inform, problems may arise. In a time when it is popular to use sharp contrast, subtle nuance may be lost. Or the broader perspective may be lacking, causing dangers or opportunities to be magnified out of proportion.

Unpleasant surprises can be avoided by making good agreements beforehand, but at the end of the day it is the programme maker who decides how the story will be told – something that healthcare institutions and caregivers do not always realise.

**Does participation in the programme cause harm to the patient and the caregiver?**

Cause no harm: this is an important moral principle in the world of medicine. When deciding whether or not to take part in a TV programme, the quality of care should carry the most weight. For example, a camera crew must not get in the way. And the camera must not intrude on the patient–caregiver relationship and patient confidentiality, for these too are essential to good care.

In practice this last point is where things often go wrong. Sometimes patients are filmed without their consent, for example when they are brought in unconscious. Their permission may be asked at a later stage, but by then their privacy has in fact already been violated. And asking the family’s permission is not an alternative – they have no right to decide about their next of kin’s TV appearances. Care institutions who decide to participate must in any case ensure that these legally determined boundaries are carefully guarded.

But even when the patient’s permission is asked when they are fully conscious, there may still be a moral problem. Is someone who has just been rushed in to the accident & emergency department in a fit state to make a well-considered decision, especially if the caregivers to whom the patient entrusts
himself behave as if the presence of the camera is perfectly normal? This is another question care institutions need to ask themselves before saying yes to the programme makers.

And it is not just the patient who may be harmed; the same applies to the caregivers. Now it is often seen as a matter of course that they will take part once the institution has given its consent. Or they swap shifts if they would rather not appear on screen. This needs to change, for they too may find there are unwelcome consequences to their participation. Images published on internet often have an unexpectedly long life. Could this have implications if caregivers apply for a job elsewhere? This demands reflection and explicit consent.

**Do the benefits of high visibility outweigh the disadvantages?**

Transparency in the healthcare sector can be a good thing. It is something we have come to expect in this day and age. But to what extent does all this TV coverage of sickness and health lead to a realistic picture? And what is the long-term effect when the viewer is constantly confronted with heroic tales and flooded with programmes about health? It can lead to unrealistically high expectations and hypochondria – and the healthcare sector will eventually find itself having to deal with these consequences.

**Do caregivers have a duty to protect patients against themselves?**

Once institutions and caregivers have decided that a TV programme is informative for the general public, will cause no harm, and has no other significant disadvantages, the decision may be made to participate. Then it is up to the programme makers to contact the patients. These are of course free to say yes or no. However, this freedom only works if the patients are approached at a suitable moment and are fully informed, including about the possibility that film material may be reused on internet or in another TV programme that might have a completely different purpose.

Do the institutions have a responsibility in this regard? They need to guard against the patients being undesirably influenced. They also need to make sure that they are not in any way involved in recruiting patients for TV programmes. It is not their job to do this, and it would be an abuse of the trust that people put in the healthcare sector and the caregiver.

**Moral problems in the spotlights**

The values of television makers and caregivers are very different. Exciting programmes for a wide public and the principles of providing good care do not always mix. Reflection on this issue has thus far been limited, or in any case somewhat opaque. This needs to change.

In education – both in the healthcare sector and the media – attention should be paid to the moral dilemmas engendered by TV programmes on sickness and health. Institutions need to give a clearer account of their decision to grant camera crews access to their patients and staff. The caregivers also need to think carefully about their responsibility to their patients. Patient associations should be transparent in how they are using television to disseminate their message. TV producers can distinguish themselves by an ethically responsible approach. And the government can stimulate clarity concerning image copyright.

A raised level of ethical consciousness in all these parties can ensure that a well-considered decision is made in each situation. The fact that many people enjoy participating in a TV programme – and watching it on television – is, when it comes to sickness and health, not a decisive argument. Only when the interests of good care are at the forefront can the production of and collaboration in a TV programme be seen as ethically responsible.
Since the Health Council published its report on ‘invasive diagnosis and treatment of the fetus’ in 1990, significant developments have taken place in this field, mainly as a result of the new options now available in non-invasive (drug) and minimally invasive fetal therapy. This report, which is complementary to the update on the state of scientific knowledge (MTA report, 2008) published by the Health Council, contains an investigation of the normative (ethical and legal) aspects of the development of this field of healthcare and science.

The fetus as a patient?

In view of the greater opportunities for treating fetal abnormalities and development defects prior to birth, it is not surprising that the fetus undergoing such procedures is described as a ‘patient’. This need not imply more than that the fetus is or can be the subject of medical treatment. But the word ‘patient’ is more than a descriptive term; it inevitably leads on to normative considerations that can come to play an independent role in the ongoing debate on what can be expected of physicians and pregnant women in this regard. The emphasis on the fetus as a separately treatable individual could imply that the pregnant woman is regarded mainly as a ‘fetal environment’ requiring optimum management. This approach threatens to sideline the pregnant woman herself and her experience of her pregnancy, and the bond she feels with her as yet unborn child. Moreover, regarding the fetus as patient could all too easily lead to the conclusion that, like every patient, the fetus is entitled to receive treatment. But whether that is so is a separate question that remains unanswered with reference to the greater treatment opportunities now available in this field.

In any case it is clear that physicians and other healthcare practitioners involved in prenatal care are responsible not only for the expectant mother and her well-being, but also for the well-being of her unborn child. If this is what is meant by references to ‘the fetus as patient’, then that appears to be a sensible message. However, the phrase ‘responsibility to the unborn child’ can refer to two things that need to be clearly distinguished from each other. The first is the well-being of the future child, and the second is that of the fetus as a fetus. There is no ethical or legal conflict with regard to the former issue healthcare practitioners must take account of the health interests of the future child. And also the pregnant woman herself can, at least from a moral perspective, be called to account in this respect. The aim is to prevent damage to the fetus that, once born, could cause the child to suffer from health problems or a diminished quality of life.

But what about the fetus as a fetus? Are physicians and pregnant women obliged to do everything they can to save the life of a fetus that would otherwise be doomed to die before birth? From a legal perspective the answer is no: the fetus is not a person entitled to treatment. Ethically, it first of all depends on how you think about the status of the fetus. Those who believe that the status of a person
with rights or interests that deserve protection is conferred to a human being only at birth will be of the opinion that interventions aimed exclusively at keeping the fetus alive should rather not be carried out. Those who believe that the fetus should be regarded as a person who deserves protection from the moment of conception or from some other point in development will have another view. However that may be, the point is that we are dealing here with philosophical convictions about which reasonable people can have different opinions. Recognizing this would be a reason to refrain from imposing a particular course of action upon pregnant women in this respect.

**Cautious development of fetal therapy**

As indicated by the recent MTA report, fetal therapy is at the cutting edge of medical science. There are a few accepted treatments for which adequate scientific evidence is available, but most interventions are still experimental.

Fetal therapy should wherever possible be developed in the context of well-designed prospective scientific research aimed at obtaining data on the efficacy and safety of new therapies. Administering innovative but as yet unproven therapies can be justified in *ultimo remedium* situations under certain conditions (including informed consent from the pregnant woman), but needs to be the subject of scientific research at the earliest opportunity. It is vital to ensure that pregnant women are not used as test subjects without adequate protection of their interests (and those of their future children). The problem of having too few patients for comparative research can be resolved by means of international cooperation between centres, something that is increasingly occurring.

Essential elements for responsible future development of the field are central and uniform registration of procedures, scientific assessment and follow-up research. A longer-term view must also be taken. This research must not only focus on the development and well-being of children who underwent fetal treatment, but also on the well-being of women involved in such procedures during pregnancy.

The prohibition on non-therapeutic scientific research on fetuses, enshrined in Article 20 of the Embryo Act, recently came up for discussion. It has recently been announced that this aspect of the law is to be revised, allowing some opportunity for such research subject to strict conditions. One of the points made in the parliamentary debate on this issue was that the research that will now be permitted must be ‘without any risk to the fetus’. This criterion is stricter than that laid down in the Medical Research involving Human Subjects Act (WMO), which allows non-therapeutic research on mentally incompetent individuals subject to the requirement of ‘negligible risk’. The question is: is this requirement too strict? What can be the reason for providing fetuses greater protection than mentally incompetent children or adults?

**Cautious decision-making**

Treatments are available for some fetal conditions that entail minimum risk for the pregnant woman or the unborn child and that can improve the prognosis so greatly that the choice is not difficult. Examples include intra-uterine blood transfusion and some forms of drug treatment. However, in many other cases the expectant mother or the couple is faced with a more complex deliberation. The desired outcome is a child born alive with the best possible health prospects. Not all pregnant women or couples may take the view that fetal therapy, that increases the chances of survival but cannot necessarily prevent some of the surviving children being disabled, is necessarily a better option than abortion (if this is still possible) or taking no action for the time being. If the procedure involves surgery, there is also the risk of premature breaking of the waters and premature birth, and so the procedure itself could lead to perinatal death or neurological damage. Consequently, decisions often have to be taken under conditions of uncertainty, even in the case of proven treatments such as
those for twin-to-twin transfusion syndrome. This is even more likely to be the case with experimental forms of fetal therapy. It is sometimes doubtful whether the treatment will provide a greater chance of healthy survival. In this situation some couples will want to do everything they can to save their child’s life, even if there is a considerable risk the child will be facing a life of illness and handicap. Others will take a different decision for that very reason, and decide not to take action for the time being or to terminate the pregnancy.

These are clearly emotionally charged decisions in which a great deal is at stake for those involved from various points of view. Counsellors who help the pregnant woman or the couple to come to a considered decision face a challenging task. A key aspect is the strong bond of sympathy that many pregnant women feel with their fetus. Many pregnant women are prepared to make sacrifices at great cost to themselves for their child if this is necessary. Counsellors need to be very attentive here. Does the pregnant woman’s choice fit in with her own experiences, values and ideals, or not? Another aspect is that some of these choices (abortion) require healthcare professionals to be as non-directive as possible, whereas for other choices this attitude would be too detached in view of the fact that healthcare professionals are also responsible for the well-being of the future child.

**Conflict situations**

It can be argued from an ethical point of view that good parenting starts before birth, and that expectant mothers may be reminded of this if necessary. This can be the case if a pregnant woman would cause her future child to suffer from a serious deficiency if she failed to undergo a proposed fetal treatment. However, this would require an accepted treatment that would evidently save the future child from significant and irreversible damage without exposing the pregnant woman herself to a serious risk. In such cases, strongly directive counselling can be morally justified, as may also be the case for further-reaching forms of coercion or even compulsion.

Whether in such cases these measures may also be justified in legal terms, is a difficult question. The problem is that the child has not yet been born, and so there are no grounds for imposing restrictions on the pregnant woman’s freedom. Some judicial verdicts have used a broader interpretation of existing legislation in order to justify measures involving coercion or compulsion applied to pregnant women who are addicted or mentally ill in order to protect the child prior to birth from health damage caused by their lifestyle. In the debate on this matter the assumption is that such measures would be legally justified only for pregnancies of 24 weeks gestation or more. The fact that developmental damage often occurs earlier in pregnancy raises the question of whether the health interests of the unborn child are adequately protected by this approach.

As an extension of this debate, the question of the justification of compulsory perinatal or prenatal interventions (Caesarean section, fetal therapy) arises. Compulsory treatment would seem to be difficult to defend from a legal point of view as we are generally dealing here with mentally competent pregnant women, which was not the case in the context referred to above. But the question of whether this option needs to be available is up for debate. Some authors argue from the principle that a viable fetus has certain rights that must be weighed against those of the pregnant woman. The question is whether the debate could perhaps be posed in terms of a less controversial argument: the future child’s interest in good health.

**Policy issues**

**FOR PROFESSIONALS AND CLINICAL PRACTICE**

- Fetal therapy should wherever possible be developed in the context of well-designed prospective scientific research aimed at obtaining data on the efficacy and safety of new treatments;
- International cooperation is vital if research of this kind is to get off the ground;
Essential elements for responsible future development of the field are central and uniform registration of procedures, scientific assessment and (long-term) follow-up research;

Preventing fetal stress and possible fetal pain must be a major issue;

The complexity of fetal therapy requires a multidisciplinary approach by a team of experts involved not only in the treatment but also in the pretreatment and posttreatment phases;

Adequate counselling of the pregnant woman and her partner is a significant challenge. Further reflection on the normative framework for this counselling is needed, especially in the light of the many and varied kinds of decisions that may need to be taken in practice. These decisions may sometimes require healthcare practitioners to adopt a non-directive approach, but there may be occasions on which it is important to emphasise to the pregnant woman that she has a responsibility for the well-being of her future child.

FOR GOVERNMENT AND SOCIETY

Preclinical animal research is important in order to determine whether human trials would be justified. Non-human primates may have to be used in such research. This is permitted under the law subject to strict conditions, but is increasingly subject to societal controversy;

Funding of long-term follow-up is a real sticking point in practice;

The changes that have been announced to Article 20 of the Embryo Act still do not appear to offer enough opportunity for non-therapeutic scientific research on fetuses;

A sustainable normative framework is needed for potential measures involving coercion or compulsion for the protection of the health interests of the future child, also with regard to cases where developmental damage is to be prevented in the early stages of pregnancy.

A complete report is also available:
See also our English version of the website www.ceg.nl; you can download the monitoring report and see what the CEG is currently working on.
Dilemmas on the doorstep. Reading early warning signs and intervention by professionals in parenting situations (2008)

The shifting roles of family and government
Every opportunity for every child. Every child wins. These are the mottos under which current youth policy is being conducted at national and local level. The focus is increasingly on prevention, with the goal that children should not only be protected from danger, but should also be able to grow up to become people who participate in society. Early warning signs are a reason for intervention, and parenting is not just a matter for the family, but for society as a whole.

This is actually not a new idea. The level of government interference in the family has always swung to and fro. However nowadays calls for earlier and more forceful intervention are being heard more and more often. There are a number of reasons for this.

Firstly, there are the statistics concerning our young people. There is no problem with the majority of our children, but according to recent estimates, 100,000 to 160,000 children each year suffer abuse and neglect. This is more than has been assumed until now. There are also reports on issues such as alcohol abuse amongst young people that cause concern. Public perception also plays a part – terrible incidents that receive huge attention from the media create moral indignation and make us all more alert to what can go wrong behind closed doors.

Secondly, there are social developments. The modern view of the role of the family is that children must be allowed to be children, but must simultaneously be brought up to become people who participate in society. People’s view of the government’s role corresponds with this – it becomes more important, not just when children are in danger, but also when they are being brought up in disadvantaged circumstances.

Added to this, there is also our ever-increasing knowledge. More and more is being learned about the effectiveness of prevention, and more validated interventions are being made available in youth policy. Incidentally, this development is also linked to the social climate – the amount of research reflects the degree of interest in early intervention.

All these influences bring the government to the family’s front door more quickly than in previous decades. However, it is not the government that rings the doorbell, but someone working for the Youth Care Agency, in youth welfare, youth healthcare, or in a school. And that person is confronted with a number of difficult moral dilemmas, where it is not always easy to know which decision will result in ‘good care’.
Conflicting values on the doorstep

In some cases it is clear that the problems in a family are so great that intrusion into its privacy does not require complex moral soul-searching. The fact that the actions taken are sometimes inadequate is not due to conflicting interests but rather, for example, as a result of flawed coordination between organisations. But there are also many cases where the moral legitimacy that justifies the social worker stepping across the threshold is less clear. This then leads to uncertainty and taking action either too soon or too late.

The first problem that creates uncertainty is the confusion governing the moral grounds for intervention. As a society, we believe in preventing or limiting damage to children, and we place the interests of children foremost, but having said that, we do not want social workers constantly on our doorsteps. This is often forgotten in the call for more vigorous intervention, even though the protection of privacy and autonomy in bringing up children are also important values. The dilemma thus created is then ‘delegated’ to the social worker who is standing on the doorstep.

The social worker’s working environment also sends out conflicting signals. The switch from non-intervention to intervention has not yet been made in all institutions and professions, with the result that there are different perceptions and practices existing alongside each other. Moreover, a good balance has to be found between intervening too soon or too late, within the constructions imposed by rules and regulations. This, too, is a difficult balancing act.

Secondly, social workers may hesitate because they are afraid of causing harm. After all, intervention is only meaningful if something good comes out of it. And social workers are not always convinced that an intervention is meaningful. For instance, some are afraid of damaging the trust they have built up with the parents or the child. They feel it is more important to maintain this trust than to report an abuse, and they sometimes overestimate their own ability to help.

Uncertainty regarding the cause of the problems (have the parents failed, or is there something wrong with the child?), and doubts regarding the availability of suitable treatment, can also result in social workers being afraid to intervene. Lack of knowledge and experience also play an important role. Staff turnover is considerable, and the larger part of the workforce is often made up of young people, whereas life experience can be particularly crucial to having the courage to act clearly and decisively. In some cases, it is better to use male rather than female social workers. In non-western immigrant families male social workers may carry more authority; however they are by no means always available.

Thirdly, social workers may be afraid of being harmed themselves. Particularly now that youth care is being put under more pressure, the fear of making mistakes is increasing. Social workers can even be held legally responsible. This can be a reason for passing requests for help on to a different agency, or for intervening too quickly. The latter sometimes gives rise to political unease, next to the call for more forceful intervention.

Moral and professional baggage for social workers

What is required to provide youth care workers on the doorstep with the moral baggage they need to act effectively? The government needs to reflect on the moral underpinning of the present, more invasive youth policy, and it must guard against violation of the boundary between what is and is not acceptable.
If there are only general risk factors present such as, for example, a family’s weak socio-economic status, then intruding on their privacy is not justifiable in itself, although prevention programmes can be offered so long as free will and the protection of personal privacy are guaranteed. However, where the risk indicators are more predictable, insistence on support is certainly justifiable. If abuse is discovered, more forceful intervention is morally justified – although even then care must be taken not to confuse cause and effect, and preference should be given to applying and exerting pressure on receiving support. The autonomy of parents is clearly not a question of ‘you either have it or you do not’. Force is reserved for cases where supporting autonomous action is not working, or where the danger to the child is too great.

It is the task of the institutions and professional groups, more than that of the government, to provide support for youth care workers, for they are the link between society and policy on the one hand, and the individual social worker on the other. Professional codes and peer review among colleagues are important instruments for providing social workers with clear guiding principles – without giving the impression that everything can be captured in protocols. Each situation requires individual consideration, and there will always be uncertainties. Good judgment, accumulated experience and treating each situation individually are indispensible. However, a consistent moral foundation can be provided that will also underpin professional actions in the long term. In order for this to be put to good use, the knowledge and experience of social workers does need to be strengthened.

It is therefore necessary to work along two lines. Coherence and dialogue are important, in order to meet the call for greater prevention and safety whilst simultaneously not losing sight of the protection of privacy. A clear moral underpinning of youth policy can help social workers to cope with this complex dilemma in a responsible, self-assured and decisive way.
Farewell to non-commitment. Decision systems for organ donation from an ethical viewpoint (2008)

Discussions on post-mortem organ donation usually centre on four decision systems: the consent system, the classic no-objection system, the compulsory-choice system and the Active Donor Registration System (ADR system). Within these systems, citizens can choose one or more options: whether they wish to be donors, whether they object to this, or whether they (explicitly) leave the decision to their next of kin.

The most important difference between these systems lies in their choice of default. Default is what happens if people do not make a choice. Under the consent system, default means no removal of organs, while the default in the classic no-objection system and the ADR system is ‘donation’. Theoretically, there is no default in a system in which citizens are obliged to make a choice: each choice is made explicitly.

This study discusses the aforementioned decision systems on the basis of four moral principles. Until now, organ donation in the Netherlands has mainly been examined from the point of view of the right to self-determination (1) and the idea that organ donation must be a gift (2). Two obligations are also stated in international literature: organ donation is regarded as a duty to render assistance in a serious emergency (3), or as a contribution to a social benefit which is to everyone’s advantage and to which everyone should contribute accordingly (4).

The discussion results in two remarkable conclusions. It is equally difficult from all starting points to find any justification for the role of the next of kin in the Organ Donation Act: the fact that they are allowed to decide if the deceased themselves have not made any choice. And the ADR system is the only one that is fully compatible with all four starting points.

**Self-determination**

In the Netherlands, if people do not make a decision on organ donation themselves, their next of kin are the ones who decide. All in all, therefore, the Netherlands has a no-objection system rather than a consent system. Or, to be precise, it has a ‘no-objection-to-delegation’ system, which means that the decision system contained in the Organ Donation Act does not comply with the right to self-determination. This right, which is interpreted as the right to have control over one’s own body, is only respected if consent is actually asked and given. Generally speaking, consent is merely presumed in no-objection systems.

In some circumstances, not objecting may be construed as tacit consent: if the law or common practice has good reason to interpret silence in this way, if the person involved is aware of this and if he can lodge an objection in a simple manner at any time he likes. In such cases, tacit consent is true...
and full consent. Although the ADR system is a no-objection system, it entirely fulfils the conditions as stated. For this reason, the ADR system is fully compatible with the right to self-determination, provided there is good reason to make donation the default. This will be discussed in more detail later on.

From the point of view of the right to self-determination, no fault can be found with the compulsory-choice system. The fact that citizens are obliged to fill in the donor form does not infringe their rights over their own bodies. It is a minor restriction of their personal freedom, but this is fully justified by the social interest of organ transplants. In the compulsory-choice system, citizens have complete freedom regarding which choice they make: they can choose donation, refusal, or (explicitly) leaving the choice to their relatives.

However, sanctions are necessary in order to induce everyone to make a choice, although the weaker the sanctions, the less people will be likely to make a choice. If the sanctions are serious, this might unfortunately result in many citizens registering objections as a protest.

The ADR system, too, can always fall back on a registered decision by the individual in question, in which the right to self-determination is likewise respected. But in this case, no sanctions are necessary, which means there is less fear of protest votes.

**Organ donation as a freely-given gift**

The view that donation should be a gift freely given for the sake of the recipient’s interests has always been an important moral starting point. According to this view, it is commendable to give, but not reprehensible to refrain from doing so. The ideal of giving freely is attractive in all respects. If it can be achieved without a great many problems, such as in the case of blood donation, the ideal of giving freely may be regarded as a moral attainment. But we are meanwhile forced to conclude that an appeal to people’s spontaneous willingness to give results in a structurally insufficient supply of organs, which means that a further appraisal is inevitable. What should have priority in an emergency: the interests of the next of kin or charitable interests? If organs are scarce, the ideal of giving freely must yield to less non-committal opinions on organ donation.

**Organ donation as an obligation**

In international literature, organ donation is sometimes regarded as a moral duty, and this can be interpreted in two ways. The first of these is classically expressed by Thomas Aquinas: it is the duty of each individual to help anyone whose life is in danger (or who is in similar dire straits) if this individual is in a unique position to provide such help and if this help merely requires him to make a relatively modest sacrifice. Since post-mortem organ donation fulfils all three conditions, this justifies making donation the default and choosing a variant of the no-objection system.

According to a second interpretation, we can regard organ donation as a social benefit which is to everyone’s advantage and to which therefore everyone must contribute. Surveys show that if the worst comes to the worst, almost everyone would like to qualify for a donor organ. Those who are not prepared to contribute after their death only increase the shortage of organs, thereby shifting the burdens attached to this – consciously or unconsciously – on to others, including living donors.

For this reason, it would be a good beginning to include a question on the donor form as to whether the person would like to qualify for an organ themselves if the need should arise. One alternative is only giving organs to patients who have registered in good time as donors. Some people feel that this would contravene one of the basic principles of health care: that this care must be given where it is needed. However, we only apply this principle because we have taken another way of ensuring that
the means of providing care are available, i.e. by making everyone legally obliged to pay premiums. A system in which care is given where it is needed and the means are obtained from voluntary contributions is unthinkable, particularly if these means turn out to be insufficient.

It is admittedly a tough measure to fully exclude people who are not registered donors. One middle course would be to only give registered donors priority on the waiting list, thereby emphasising that it is reasonable to contribute to a system from which everyone can benefit.

**Solidarity**
Both conceptions of personal obligation provide sound arguments in favour of abolishing non-commitment. Organ donation should no longer be regarded as a gift, but as a ‘normal’ contribution to a collective effort to alleviate a dire need: in short, it is a form of solidarity.

Under normal circumstances, citizens can fulfil their solidarity obligations by contributing their possessions or by working. But in the case of organ donation, the contribution in question is one’s own (dead) body, which is why we can postulate that despite the fact that a moral duty exists, everyone must be able to choose whether they will fulfil this duty. However, the existence of this obligation does provide a cogent reason for making donation the default. Since there is a considerable difference between a decision concerning our living bodies and one which merely concerns our dead bodies, nobody objects to the public prosecutor ordering an autopsy without asking permission. Fortunately, however, we do not need to go as far as that in order to do justice to solidarity obligations: under the ADR system, donation is chosen as the default without any infringement of the right to self-determination.

Even without appealing to solidarity obligations, there is a reason for making donation the default. The fact that society has a legitimate interest in increasing the number of available post-mortem organs is sufficient. Since the introduction of the Organ Donation Act, legislation on this point has been halting between two opinions.

**The position of the next of kin**
Looking at the situation from the four moral principles, the right of the next of kin to decide on donation is only defensible if the deceased has explicitly left the decision to them. In most countries, however, the next of kin also have this right (at least in practice) if the deceased has not expressed a personal choice. The strongest justification for this is that generally speaking, the next of kin have a greater interest in the decision than the deceased themselves. The interests of patients waiting for an organ are admittedly even greater, but giving priority to the next of kin is defensible due to their special relationship with the deceased. That is why donation should still remain a gift: if not from the donor, then from the next of kin.

However, this argument is problematic for two reasons. To start with, legitimate partiality should not be carried to the extent that people whose lives are in danger are abandoned to their fate. And secondly, if the next of kin were given the right to decide, this would also enable them to overrule the deceased’s explicit consent. This is generally rejected in the Netherlands and has therefore been precluded by the Organ Donation Act since 2006.

**Rewards**
Besides the debate on legal systems, there is a great deal of international discussion going on with regard to (financial) rewards for organ donation, such as a contribution towards the cost of funerals or cremations. This would not involve the payment of a market price, but would rather be a token of...
appreciation which would also have an encouraging effect. Two objections to this proposal are normally put forward. The first objection claims that this would adversely affect the altruistic nature of the 'gift' of organs, although the question is whether this is actually true. After all, we do not consider the altruistic nature of donations to charity to be undermined by the fact that they are tax-deductible. Moreover, the question here, too, is which issue should be given priority: maintaining the purity of altruistic motives or alleviating existing need.

The second objection to any form of reward is that, by turning dead bodies or bodily parts into 'merchandise', we are showing a lack of respect for such dead bodies and therefore – by association – for people. However, it is not certain that organs actually do have this symbolic value in our society: this differs from person to person and from organ to organ. A cautious government policy would then seem to be indicated in which health insurers are given the choice of rewarding the next of kin, and the next of kin are given the choice whether to accept.

**Choosing one of two options**

If the right to self-determination were the sole deciding factor in our choice, we might consider implementing the compulsory-choice system. This can easily be combined with priority for donors on the waiting list, which would only make the consequences for others of the choices one makes apparent. It can easily be combined with a reward system as well.

Nevertheless, those who acknowledge that there are compelling moral reasons in favour of donation will naturally want to make donation the default and therefore choose a variation of the no-objection system, preferably the ADR system. In order to place more emphasis on the obligatory nature of the decision, the obvious solution would be to give registered donors priority on the waiting list in this case too. A reward system, on the other hand, would not be logical: one does not reward people for doing what they ought to do.

It is important that the choice of one of these options is made clearly and consistently, because the way in which society regards donation has an effect on the choices people make. That is why the prevailing idea of a 'donation to charity' should consistently be replaced by 'a free choice with consequences attached' or 'a contribution to solidarity in society'.

**Defaults make a difference**

Recent insight into the way in which people make decisions indicates that the choice of defaults is of immense significance. In that case, the legal default must constitute more than a dead letter. International comparisons show that there are countries with a no-objection system where the return is (even) lower than in the Netherlands, given the potential number of donors. However, this comparison also suggests that the countries with the best results are countries with a no-objection system. This is probably due to the fact that the legal system in the second group of countries prescribes a different approach to the next of kin. If the deceased has not registered any objection, the next of kin are not asked an open question. In such cases, conversations are based on an assumption of donation. If the next of kin object, the hospital authorities will try and remove these objections and only respect them if the next of kin continue to maintain their objections. The way in which the next of kin can be approached is determined by the decision system.

When amending the default, it is of essential importance that hospitals are encouraged to hold talks with the next of kin of registered donors on the basis of this assumption. There is good reason to believe that the percentage of refusals on the part of next of kin will then decrease considerably.
**Living donation**

There is far-reaching consensus on the ‘decision system’ for living donation. Living donation is only possible on the basis of a voluntary and well-considered decision to do so on the part of the donor. After all, the right to determine what happens to one’s own body is an extremely important factor with regard to living bodies.

This need not deter the government from appreciating and facilitating living donations, which means first and foremost that the compensation scheme for loss of income should be a generous one. It also means that the government should enable transplant centres to mediate where necessary when seeking donors.

The crucial question in the case of living donation is what would justify doctors in carrying out stressful surgery on people who have no personal health interest in such surgery, and who even run certain risks. After all, such surgery turns healthy people into patients. Some people claim that the consent of the individual concerned is sufficient, while others maintain that the donor’s interests in a wider sense can justify the operation. However, there is a third opinion, and this is the most convincing: the justification for doctors lies in the special relationship between donor and recipient which gives them a specific responsibility towards one another.

If we regard the matter in this light, living organ donation to unknown persons is a problem. To justify this, we would have to acknowledge that the donor is able to assume specific responsibility for people in distress as a result of a ‘vocation’, and in that case, the donor would have to take the full initiative. This precludes such donors from selecting a particular recipient or group of recipients to whom they wish to donate their organs, since they do not have a specific responsibility towards that particular recipient (or recipients).

**Should living donations be financially rewarded?**

The most controversial issue is the option of rewarding living donors. For example, the authorities could take over the costs of compulsory health insurance for such donors during their lifetimes. In this context, the appeal to the symbolic value of the human body gains ground among the objections to ‘commercialisation’, since this is more apparent in the case of (parts of) living bodies than of dead bodies. Moreover, there would no longer be any justification for doctors to cooperate with donors acting primarily out of financial motives. Cutting into a living body is entirely different if the donor feels a special duty of care for the recipient then if the ‘donor’ would like to be exempted from paying health care premiums.

The proposal to exempt living donors from payment of health care premiums assumes that living donations which are already taking place will continue to the same degree and from the same motives. This is unlikely, however: donors may also withdraw if others offer their organs. This means, however, that we cannot know in advance what sum would be sufficient to obtain the desired supply: this would be determined entirely by the market.

The matrix below shows how the different decision systems for organ donation should be evaluated using the four moral principles discussed. The matrix also indicates whether these principles provide scope for the next of kin’s right to decide in cases where the deceased has not registered any choice with regard to donation, for financial incentives, or for giving priority to registered donors on the waiting list.
In a supplemental report I will discuss several other variations on the decision-making systems covered in the main text.

4. One proposal is a variation on the current system in which it is possible to record consent for donation but not a decline of consent. If no consent is found in the donor register, the next of kin decide.

What are we to make of this system? While it may be possible to continue to set out a decision to decline consent in a binding statement of will, this still deliberately makes it difficult for an individual to preclude the removal of his or her organs. This is the crux of this system. As such, the system does not respect the right to make decisions over one’s own body, that right evidently being subordinate to the interests of the next of kin. But in that case, it is not at all clear why consent should then suddenly be assigned a major, and perhaps even decisive, significance. This cannot be based on the right of self-determination, being that the system sets aside this right in favour of the interests of the next of kin. But neither can it be based on the interests of organ recipients, because if so this would involve securing organs even when the deceased has made no decision on the question. In short, this system cannot support any coherent justification.

5. A proposal has been made to add the following option to the present range of choices on the donor form: "I cannot make a decision at this time; ask me again later."

This proposal suggests that there should be more choice. But until a full-fledged mandatory choice system is introduced, anyone can always postpone the decision, and the option to not make a tacit decision is simply not there. If the idea is to make an urgent appeal to people to make some sort of decision in the short term, this would be better stated explicitly as such. Additionally, a repeat mailing would have to be sent to everyone who has not explicitly made a choice.

The other proposals are variants on the ADR system.
6. The first suggestion is to remind the populace at regular intervals that they can change their registration, possibly through annual information campaigns, or by explicitly pointing out this option to people applying for or requesting governmental documents such as a passport, driving license or certificate of good behaviour. Implementation of this proposal will have a number of different effects, and whether the net result would be an increase in the number of registered donors is unclear. What can be said is that this proposal would have two welcome effects.

Whatever pains are taken in the ADR system to inform people of the impact of not returning the donor form, there will always be people with whom this information does not sink in, and regular reminders will help to minimise this number. A reminder mailing to anyone who does not respond is still the most effective remedy for this issue.

A second positive effect is that even if tacit consent constitutes genuine, full consent, many people will still consider it as a sort of “inferior” consent. The more that people reflect on their status at regular intervals and make a deliberate decision to either change or not change their status, the more this will increase the perceived value of the tacit consent, and accordingly, the perceived legitimacy of the ADR system.

7. Some, including the Royal Dutch Medical Association (KNMG), have proposed making a distinction in the donor register for the ADR system between consent explicitly given and tacit consent. This information would then have to be passed on to the next of kin. There are a number of problems with this recommendation. Introduction of the ADR system is justified in part because the system creates the conditions under which tacit consent can constitute genuine and full consent. Recording two types of permission implicitly acknowledges that tacit consent is consent that is “inferior” by nature. Consent, however, is a category that does not allow gradations: either you consent or you don't; you can't do it half-way.

Making the distinction avoids the “dilution” effect that explicit permission would be exposed to (see section 16). But tacit consent actually promotes this effect, and there is no reason to assume that the net result of the two effects would come out positive.

8. It would, though, be meaningful to distinguish between the two types of consent if different legal effects were attached to them. Some have proposed interpreting the failure to return the donor form as follows: “I consent to the removal of my organs, so long as my next of kin allow it.” If that is the case, then this option should also be included on the donor form as an explicit choice.

Where exactly does this leave the next of kin? This cannot allow the person in question to leave a free choice to his next of kin that he does not wish to have any influence on himself. Nor can the intention be that the next of kin can state that the deceased actually felt differently than what his tacit registration implies: under the ADR system, the individual is personally responsible for ensuring that his registration is an accurate reflection of his wishes. This means that the correct interpretation of the “yes, unless” formula must be: “I give consent for the donation of my organs unless it becomes apparent that my next of kin have overriding concerns against it.” Ideally, then, this formulation should also be used on the donor form.

In terms of the right of self-determination, the addition of an extra option can only be welcomed, all the more so because this option will presumably be the choice of a large portion of the population. But does this really do sufficient justice to the interests of organ recipients? As an
expression of the standard that donation is desirable from a moral perspective, the "orthodox"
ADR system should be viewed as preferable.

That said, this variant does still retain the most significant advantages of the ADR system. Specifically, there remains a style of approach to the next of kin by which donation and decline of consent are not presented as choices of equal value, but that donation is the basic premise that should only be departed from in the case of "overriding concerns." Additionally, looking at today's Netherlands this interpretation of tacit consent by the population in general and by the next of kin in particular may be easier to accept.

**A complete report is also available:**
See also our English version of the website [www.ceg.nl](http://www.ceg.nl); you can download the monitoring report and see what the CEG is currently working on.
Appropriate evidence. Ethical questions concerning the use of evidence in health care policy (2007)

The advance of scientific evidence

Research results are playing an increasingly important role in the decisions taken about medical treatments. In recent years an extensive system has been developed for this purpose in which results from different types of research are awarded a different value from 'hard' to 'soft' evidence. If there is enough hard evidence for the effectiveness of a treatment then this will be included in a professional standard.

This standard will subsequently serve as the guiding principle, despite the continuing importance of the patient's input and the fact that it is the health care professional who will ultimately decide whether or not the protocol should be used for the patient concerned. Therefore scientific evidence alone is not enough but instead forms one of the three aspects of what is termed evidence-based medicine.

Yet as the term suggests, evidence obtained from research plays an important role. Scientific knowledge has a high status, the number of publications is still rising enormously and the system of evidence-based medicine used in health care is also starting to penetrate public health policy, where it is also increasingly being used to support decisions with scientific knowledge.

An example of this is the drawing up of the basic health insurance package. Yet interestingly, scientific knowledge scarcely plays a significant role in the drawing up of the supplementary health insurance package. There the wishes of the patient are the decisive factor: health insurers provide packages that meet consumer demands. Therefore in practice these contain quite a number of treatments for which no evidence whatsoever is available.

These developments raise the question as to what is an appropriate role for scientific evidence within the current health care system and current public health policy. Is evidence according to the criteria of evidence-based medicine the best way of substantiating the value of all forms of care? And how should the three elements of evidence-based medicine – the best available knowledge, the judgement of health care professionals and the preferences and needs of patients – relate to each other to ensure an optimal quality of health care and good health care policy? That is the key question considered in this monitoring report.

The price of evidence

There is much to be said for trying to support medical decisions with scientific evidence. In the history of evidence-based medicine, fine examples can be found of enormous quality improvements realised as a result of working with tried and tested methods. Methods have been developed for this
approach, and protocols ensure that the latest findings are made available for health care professionals; with the current growth in knowledge it is impossible for individuals to keep abreast of the latest developments, let alone assess these on the basis of their merits. The evidence-based approach means that patients can be assured consistency in their treatment, irrespective of the health care professional treating them.

In public health policy, a legitimate effort is also being made to support decisions with scientific evidence. Policy makers also want to do what works and to discard things that are pointless or counterproductive. Information about the effectiveness of a measure can be used to determine whether the benefits justify the costs. The approach of evidence-based medicine provides leads for this.

However, there are catches in the quest for increasingly more and harder evidence. One problem is that not all forms and elements of health care can be easily investigated according to the methods prescribed for evidence-based medicine. The obstacles can be methodological but also financial and ethical.

For example, the efficacy of a specific medicinal product can often easily be tested in a randomised controlled trial (RCT) with a large group of study subjects and a control group. Such investigations are very expensive but can usually be financed by the pharmaceutical industry (even if that in turn is reflected in high costs for medicinal products – evidence is anything but cheap). This is not the case where preventive measures are concerned which do not bear any immediate effect, or for the treatment of elderly patients who suffer from several conditions at once. Then it is difficult to select a stable study group and there are many factors that cannot be controlled but which can influence the outcomes. Finding an interested party willing to finance the research can also prove difficult.

Another completely different area is the elements of health care that are usually referred to as guidance, attention and ‘presence’. In these cases the nature of the ‘intervention’ demands a different form of evidence than that generally accepted in evidence-based medicine.

There is a risk that where it can be easily proven that certain forms of care and measures result in health gain then these will receive greater attention, whereas others will suffer a loss of status, and eventually resources as well, due to a lack of hard evidence. That danger will definitely be present if the methodology of evidence-based medicine is used in an increasing number of contexts. Then not-proven interventions will increasingly come under fire.

Moreover, practice has taught that people easily forget that there is a fundamental difference between ‘not proven that it works’ and ‘proven that it does not work’. Further it should also be remembered that only 10 to 25% of current medical treatments are based on evidence. At present, efforts to obtain evidence seem to outweigh the actual evidence obtained.

If despite these nuances the focus still comes to lie on hard evidence then, and certainly where that cannot be obtained, important values within health care could be lost. In some cases searching for evidence of health gain is not even relevant. Paying attention, not being in a hurry, a kind word: we still value such things, even if their ‘effectiveness’ can never be proven.

**The variable role of evidence in health care insurance packages**

What does all of this mean for the decisions about treatments that are included in the basic health insurance package, and the treatments in the supplementary package? Here we find the remarkable
situation that evidence is increasingly becoming the guiding principle in the basic health insurance package, whereas for supplementary packages the wishes of the consumer play the decisive role.

In the basic health insurance package there is the danger that the hard form of scientific evidence will acquire a great deal of weight, even though 'proven efficacy in a research situation' is not the same as 'practically applicable in the complex daily reality'. Such a scenario also limits the judgement of the health care professional and the preference of the patient. And with this the quality of care provided will eventually be put at risk.

The solution is to search for types of evidence that are appropriate to each form of care. In many cases that can be hard evidence, according to the methodology of evidence-based medicine. However, other types of research can also yield appropriate evidence. Furthermore, these can help to prevent the development of a competition for evidence that pushes up the costs of health care even further still, as hard evidence is expensive whereas an effective intervention can often be investigated in another manner. After all, a significant clinical effect can be demonstrated even with a small group of patients.

Whereas in the basic health insurance package there is a danger of too great an emphasis on a certain type of evidence, in the case of supplementary packages evidence scarcely gets a look in. And that is hardly surprising. After all these packages are aimed at enabling people to insure themselves for care that does not satisfy the criteria for the basic package. Accordingly these packages contain a wide variety of care forms, from dentistry to health resort trips, and for a considerable number of the treatments reimbursed, there is no evidence that these work. This applies, for example, to the alternative therapies included in virtually every supplementary package but also for the medical check-ups that are increasingly being offered.

Of course people are free to take out insurance for non-proven treatments. Perhaps there are occasions when the supplementary package is a useful parking space for non-proven treatments that are rightly or otherwise – further research will need to show this – excluded from the basic package. On the other hand, the fact that insurance can be obtained for some forms of care unduly accords these a status: 'if I can obtain insurance for it then it must work'.

An even more difficult problem is where treatments are offered despite evidence that these do not work. Such cases also illustrate how the differences in levels of evidence between the basic package and the supplementary package can place the health care professional in a difficult situation. Evidence-based working, which is further the creed of clinical practice, would not appear to apply in certain cases. That leads to a strange fragmentation, which could ultimately lead to the confidence placed in the health care professional being damaged, even though a good therapeutic relationship is crucial for the quality of care provided.

Solving this problem therefore requires a greater role for evidence in the drawing up of supplementary packages. Such a use of evidence should lead to the exclusion for treatments that have clearly been proven not to work. Combining the sale of worthwhile and not-proven treatments is equally undesirable.

Towards the use of appropriate evidential value
The differences between the basic and supplementary packages in terms of the importance attached to evidence could be reduced. However it remains obvious that in the basic package, where solidarity continues to be an important element, other, heavier advice will be considered more appropriate than in
the supplementary package, where the consumer's choice is the decisive factor. Yet for the basic package the current definition of appropriate evidence can be extended. This would allow justice to be done to the complexity and value of treatments that are more difficult to capture in terms of hard figures.

A complete report is also available:
See also our English version of the website www.ceg.nl: you can download the monitoring report and see what the CEG is currently working on.
Our society is facing a serious shortage of organs being made available for transplant. The number of post-mortem donations is continuing to fall in spite of what are often successful efforts made when counselling relatives of people who have died. Live donations, of kidneys in particular, are increasingly common but do not resolve the shortage.

This situation is translated into a great human and social cost. The cost is increasing rather than reducing, as people are more inclined to resort to illegal trade in kidneys from live donors, with all the abuse that this involves.

That is why ways of increasing the number of available organs are being explored. So far, little attention has been given in policy to one possible option: financial incentives for organ donation. This is easily explainable: the concept of paying for organs can initially appear repellent. The general view is that organs must be freely given. That is also the legal position.

Are financial incentives for organ donation morally justified?
The question should really be whether we can ignore opportunities that, if carefully considered, can be integrated into our value-system from an ethical point of view and that are also worthwhile in practical terms, given what is at stake. Now that the drawbacks of the current situation are becoming more pressing, the question is whether we can afford to refuse to discuss the possibility of reward.

The time seems right for an in-depth ethical investigation of this topic. Two forms of donation need to be considered: post-mortem organ donation, and donation of a kidney by a living donor.

Rewards for post-mortem organ donation
There are two ways of encouraging post-mortem organ donation by allowing reward: rewarding someone for registering as a donor, or rewarding his or her surviving relatives when the organ is taken.

An ethical analysis shows that there are no insurmountable ethical problems in either case. However, there are objections and risks. For example, would not certain measures, such as handing out a gift on registration or paying a considerable sum of money to surviving relatives, turn out to be counter-productive or lead to strategic behaviour? The stumbling-block here is therefore effectiveness rather than any moral objection. Another problem is the distorted cost/benefit ratio.

These objections apply less forcefully to incentives that do not take the form of cash payments but rather of discounts on medical expenses or funeral costs, for example. The link with healthcare is
retained, which is not the case for something like a free passport. This also applies to the suggestion of a non-material incentive such as giving registered donors some advantage on waiting lists. In the light of this, the following incentives for donor registration should be considered:

– giving a one-off discount on health insurance premiums, and
– giving registered donors a slightly higher place on waiting lists for any future organs they may need to receive themselves.

When the issue of donation actually arises, the benefit may come mainly from reducing the number of times that surviving relatives refuse to have their loved one's organs taken. The following incentives should be considered:

– rewarding surviving relatives who consent to organ donation, for example by paying funeral expenses, and
– offering (even) more support to professionals so that they can give good general information, help people taking decisions when they are about to die, and communicate with and provide counselling to surviving relatives.

Though these measures may have some impact, financial incentives to encourage post-mortem donation are unlikely to produce a really significant effect. That is because the number of organs available for post-mortem donation is limited and continues to fall.

**Incentives for (kidney) donation from live donors**

Live donation has become increasingly important as the number of organs available for post-mortem donation declines. The question which needs to be addressed is how financial incentives can help to increase the number of organs that are available.

The ethical analysis shows that under certain circumstances payment is morally justified, provided at least that the fundamental basic principles of it being a voluntary act and of equal access are maintained. Payment and the voluntary nature of the act do not seem to be mutually exclusive, and payment and altruism, an important feature of our donation system, can easily go hand in hand. There are therefore no decisive objections that by definition rule out the provision of financial incentives to live organ donation. There are certainly a number of difficulties, but these can be addressed by attaching conditions to implementation.

The best option is to arrange for life-long payment of health insurance premiums for live donors. This option does most justice to the moral intuition of many people who do not see organs as something for which you should receive money. Another benefit of exempting donors from paying health insurance premiums is that it is not so evident that it would lead people in financial difficulties to decide to donate an organ.

By making a financial incentive of this kind available the government further emphasises its commitment to reducing the shortage of donor organs, expresses the position that donation is morally justified and is valued by society and that it is doing what it can to cover all health risks.

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Considerations pertaining to neonatal life termination (2007)

Life termination causing or hastening death by the administration of a substance intended to have that effect – is a criminal offence in the Netherlands, which may constitute manslaughter or murder. However, under certain circumstances, a doctor who ends the life of a neonate may justify his/her action on the grounds of force majeure in the form of 'necessity'. Such justification is legally acceptable if the neonate’s health status is such that the baby’s suffering is or will become so severe that the doctor’s duty to alleviate that suffering outweighs his/her duty to preserve the neonate’s life.

It is believed that there are several dozen cases of neonatal life termination a year in the Netherlands. However, few such cases are reported – probably at least partly because of the uncertainty that exists concerning the conditions that must be satisfied in order to support a claim of force majeure. With a view to improving this situation, the State Secretary for Health, Welfare and Sport and the Minister of Justice set up an Expert Committee on 1 September 2006. This Committee’s case review findings are taken into account by the Public Prosecutor when considering whether to prosecute doctors in life termination cases.

The State Secretary and Minister have indicated that the Expert Committee may conclude that due care was exercised in a life termination case if: on the basis of medical knowledge, the neonate’s suffering was deemed to be intolerable and hopeless; the parents consented to the life termination; the doctor properly informed the parents about the diagnosis and prognosis and they collectively concluded that there was no other reasonable means of resolving the situation; the doctor consulted at least one other independent doctor or treatment team; and the life was terminated with appropriate medical care.

The Expert Committee’s role is to further develop these criteria on the basis of casuistry and to operationalise them. This monitoring report addresses the general issues requiring attention in the context of that process. It describes several ethical dilemmas and indicates how medical science can help to resolve them.

In the Netherlands, there is a degree of consensus that neonatal life termination can sometimes be acceptable following a justifiable decision to withhold or withdraw treatment. Such a decision may be taken if treatment offers no prospect of survival or merely the prospect of survival with a very poor subsequent quality of life. If, under such circumstances, death is unlikely to swiftly follow the withholding or withdrawal of treatment, thus giving rise to an emergency situation, life termination may be justified. The consensus that developed within the medical profession in the 1990s acquired a jurisprudential confirmation through the Prins and Kadijk cases.
More recently, the Groningen Protocol has been developed to cover a different situation, namely life termination outside the context of life-prolonging treatment. The protocol is based on the principle that a doctor has a special responsibility in relation to the subsequent life of a neonate that is suffering seriously or faces the prospect of a life characterised by serious suffering, regardless of whether life-prolonging treatment has previously been provided. The extent to which agreement exists on this point remains to be seen. The reports produced by or in conjunction with bodies representing the medical profession in the 1990s give no support to the idea of life termination outside the context of life-prolonging treatment, and no precedents have yet been created in case law. Furthermore, whether the State Secretary and the Minister deem such life termination acceptable remains to be seen. It is therefore desirable that a standpoint is defined on life termination outside the context of life-prolonging treatment and that the medical profession updates its earlier reports to cover this issue.

The Netherlands is one of the few countries where it is possible to approximate the incidence of neonatal life termination and indicate the circumstances under which it occurs. The relevant data come from evaluation studies into the practice and review of euthanasia. Nevertheless, we do not have a full picture of what takes place in the Netherlands. The reasons for this include the absence of a precise definition of life termination and a paucity of information concerning the particular features that characterise cases in which a substance is administered with the specific aim of shortening life.

In the context of the evaluation studies, a death was not classed as life termination if the administration of a substance merely hastened a death that was imminent following the withholding or withdrawal of life-supporting treatment. The latter approach is consistent with the view held by many doctors that, if death is inevitable within a matter of days or hours, the administration of a life-shortening substance constitutes palliative care, rather than life termination. Legally, however, the administration of a substance with the aim of hastening death is life termination even under such circumstances, and should accordingly be reported as such. The reporting of such deaths is also desirable for reasons of transparency. A medically induced death is not life termination only if the substance that brings it about is medically indicated, e.g. for the professionally justifiable management of pain. However, it is not clear how often the administration of a substance with the express intention of hastening death following a decision to withhold or withdraw treatment is medically indicated.

To obtain a good picture of the incidence of neonatal life termination, it is best to work on the basis of the legal definition of life termination: the administration of a substance with the aim of hastening death – either following a decision to withhold or withdraw (potentially) life-prolonging treatment or under other circumstances. Furthermore, greater insight is needed into the features that characterise life termination cases, such as the health status of the neonate, the factors considered by the doctor and (where relevant) the nature, dosage and duration of the medication administered.

According to the assessment criteria laid down by the State Secretary and Minister, life termination can be acceptable in cases of hopeless and unbearable suffering. Such suffering may occur in two types of situation. First, where it is clear that the neonate will die before long, and the degree of suffering is felt to justify deliberately expediting the inevitable. Second, where the neonate could be kept alive, but there is no prospect of any improvement in the child’s health sufficient to enable it to lead an independent life. However, the State Secretary and Minister also indicate that life termination may be justified only by acute suffering. It would therefore seem that, even in the second situation described, acute suffering must be present in order to warrant life termination.

Because acute suffering is the factor most likely to create an emergency situation, it would seem obvious at first sight that the presence of such suffering should be a precondition for life termination. However,
arguments can be advanced for sometimes countenancing life termination where such suffering is not present. The reason being that a doctor has a duty not only to alleviate suffering resulting from an illness or abnormality, but also to prevent it. A situation could arise where a neonate faces the prospect of such serious suffering that the doctor believes that his/her duty to prevent that suffering outweighs his/her duty to preserve the infant’s life. Under such circumstances, the doctor may consider it irresponsible to defer life termination until such time as the suffering becomes hopeless and unbearable. Furthermore, acute suffering is not a precondition for withholding or withdrawing treatment. If it is a precondition for life termination, a doctor who does not wish to be responsible for prolonging the life of a neonate with a bleak prognosis is liable to be cautious about initiating life-prolonging treatment.

In view of the foregoing, the Committee favours refinement of the principles underpinning the requirement that acute suffering be present.

Withholding or withdrawing life-prolonging treatment – and life termination – may be considered, the State Secretary and Minister indicate, if it is anticipated that the quality of the neonate’s future life (as perceived by the neonate) is likely to be very poor. In the Netherlands, it is accepted that future quality of life may be assessed by taking account of the anticipated level of suffering, the neonate’s life expectancy, the unpleasantness of the associated treatments, the scope for communication, the prospects for independence and the probable level of dependency on the medical care system. However, there remains no consensus regarding the application of this principle and the significance and weighting of the various criteria require further examination.

Furthermore, given the inherent value of life, it is desirable that the formulation of long-term health prognoses and the assessment of their functional significance for the neonate be evidence-based as far as possible. However, evidence is scarce. More research is therefore needed into the lives of children born with very serious health problems. It is also advisable that the medical profession should look into the possibility of using the findings of such research as the basis for developing guidelines on the formulation of decisions in connection with conditions of various types.

However, there is inevitably a degree of uncertainty attached to any assessment of a neonate’s future quality of life. Consequently, doctors need to be cautious when considering either withholding/withdrawing life-prolonging treatment or life termination on the grounds of future life quality. This is not to diminish the ethical and legal principle that medical treatment that may not be expected to benefit the patient is inappropriate and should be terminated. One of the conditions for life termination is that the doctor and the parents have collectively concluded that there is no other reasonable means of resolving the situation. However, in the debate surrounding neonatal life termination, relatively little attention has been given to alternative means of alleviating the suffering of neonates with very serious health problems. Greater emphasis therefore needs to be placed on palliative sedation and on a more cautious approach to the commencement of life-prolonging treatment.

The Expert Committee’s role involves reviewing not only neonatal life termination cases, but also abortions performed after the twenty-fourth week of pregnancy, if the foetus had a chance of survival. It is in principle a criminal offence to perform an abortion so late in a pregnancy. However, a doctor may justify such a procedure on the grounds of force majeure in the form of an emergency situation if a woman asks for a termination on the grounds that the baby she is carrying will be born with a serious medical condition. The State Secretary and Minister have indicated that the Committee may conclude that a doctor has acted with due care in such a case if: no doubt surrounded the diagnosis or prognosis, from which it was clear that the baby would be born with a condition whose postnatal treatment would be judged medically pointless; the foetus was experiencing hopeless acute suffering or would inevitably have faced hopeless suffering;
the mother expressly requested termination of the pregnancy because of the physical or psychological burden placed on her by the situation; the doctor properly informed the parents about the diagnosis and prognosis and they collectively concluded that there was no other reasonable means of resolving the situation; the doctor consulted at least one other independent doctor or treatment team; and the abortion was performed with appropriate medical care.

In this context, ‘acute suffering’ implies the presence of foetal pain. Because many questions still exist regarding the perception of pain by foetuses and the feasibility of gauging the seriousness of such pain, additional research into this matter is desirable. The prospect of hopeless future suffering may be assessed by reference to the same focus points used to support decisions regarding the provision of life-prolonging treatment to neonates and neonatal life termination. However, the uncertainties referred to in the latter context apply equally in this context. So, again, further standpoint definition and research are desirable.

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Social pressure to get more information about the quality of healthcare is increasing. This has also become a major priority for Government policy in recent years. The idea is for 'performance indicators' to be used to demonstrate the quality of care and allow comparisons to be drawn, so that all parties concerned can immediately see where care is up to scratch and where it is deficient. This process has two aims: transparency, and improving quality. Society must be able to see how public funds invested in healthcare are spent. This should offer choice to patients and insurance firms, and encourage healthcare providers and professionals to improve the quality of the care they provide.

It is clear that a fresh stimulus for improving the quality of healthcare was needed. This is not to say that nothing was done in this area in the past. The original design of the Healthcare Facilities Quality Act expected healthcare providers and professionals to put their quality systems in order themselves. In practice, this did not seem to work properly. The new approach (highlighting differences in quality and introducing external stimuli) should change this situation. It is expected that healthcare providers and professionals whose performance is poor will want to avoid damage to their reputation or a loss of market share. They will hope to achieve better results in a subsequent assessment, even if they may lack the internal motivation to improve quality. This effect could be enhanced even further by the use of (financial) rewards and penalties for high and low scores.

The question of whether this commercial approach, which has been introduced into other areas of public service over the past few years, is an effective means of achieving both aims (transparency and quality improvement) is a matter for often strongly-polarised discussion. Those in favour of this approach seem to dismiss the possibility of unwanted effects, while its opponents are already convinced that no good can come of it. An objective debate is vital if policy in this area is to be developed rationally. This report therefore hopes to make a contribution in the form of scientific data and an ethical analysis.

Performance indicators
Performance indicators are measurable elements of healthcare provision that act as a possible pointer to the quality of care. They act as signals: low scores signal that something might be going wrong, and that further analysis is needed to find out whether this is indeed the case. Indicators have to be reliable and valid if they are to fulfil this signal function adequately. By 'valid' we mean that they must actually measure what they are supposed to measure.
Findings of literature review

First, the facts. What can scientific research tell us about the effects and possible side-effects of the public use of performance indicators in healthcare? We have performed a systematic literature review to answer this question in our report. This review concentrates purely on clinical healthcare. We looked for publications addressing the effects of revealing performance scores on the behaviour of institutions and healthcare providers (whether or not quality improved, other behavioural effects); the effects of forms of (financial) rewards and penalties attached to these scores; the effects on the choice patterns of patients, insurance companies and referring doctors; effects on costs and bureaucracy.

The findings of the literature review show that the assumptions underlying the public use of performance indicators, and the expectations as to the effects of this approach, are not at present based on sound scientific evidence. With regard to encouraging better quality, we did find that this approach had some effect on the performance levels of institutions. Quality improvement initiatives were introduced after publication of performance scores that could reflect badly on the institution's image. But we found no evidence of this effect in terms of individual healthcare providers. When we found public reporting to have an effect on behaviour in this group, it seems that the effect does not take the form of quality improvement but of strategic behaviour, such as refusing high-risk patients or manipulating data. It does appear that the introduction of reward systems can have a beneficial effect on the behaviour of healthcare providers, but more research is needed to find out how this instrument can best be designed.

We have also found little evidence to support the expectation that patients, insurance companies and referring doctors would be guided by a comparison of performance scores when making choices. Patients do seem to be interested in the results of performance measurements, but they make only limited use of them when choosing among various healthcare options. They seem to give greater weight to the experience of people they know. Little research has been done into the choice behaviour of other parties that make choices. Insurance companies and referring doctors appear to have little faith in public performance figures, and so make little or no use of them.

We have little information as to the costs associated with public reporting and the implications of this approach for the administrative burden ('bureaucracy'). However, it is likely that there would be an increase in this burden in the early stages. It may well be that more efficient methods of data collection would reverse this trend eventually, but that is by no means certain at present.

Ethical aspects

The second part of the report looks into relevant ethical aspects of the public use of performance indicators. We start by clearing up the misconception that the requirement for public accountability is in conflict with the idea of professional autonomy. ‘Autonomy’ is not a green light to professionals allowing them to disclaim all responsibility for their actions. Professional autonomy and professional accountability are in fact two sides of the same coin. The room for manoeuvre in terms of autonomy is that which allows healthcare providers to offer their patients the best possible care. Society is entitled to demand that this is reflected in healthcare outcomes.

The principle underlying the new Government policy is that self-regulation in this area is too lax. The requirement to publicly report performance scores that can be compared with one another should bring into play a mechanism in which external stimuli (reputation, market share, rewards) also encourage less strongly-motivated institutions and professionals to make a serious effort to improve their quality. From an ethical point of view it is important that professionals are addressed differently.
The approach should focus not primarily on their intrinsic motivation but principally on their sensitivity in terms of their image and economic benefits. The use of such stimuli can certainly be sensible if it has a positive stimulating effect. But our literature review also found indications of a negative effect on the motivation and behaviour of professionals. The moral implications of the relationship between the positive and negative consequences of the use of external stimuli are far-reaching. Healthcare professionals are not required to be saints; however, the core of their professional identity is determined by their focus on the well-being of other people. Undermining this would cause damage to society that would be difficult to repair.

The new role that patients would play in the new Government policy, i.e. 'healthcare consumers exercising choice', is also associated with a moral risk. It raises a contemporary moral ideal, that of self-determination. Another important aspect is that a patient's choices can help encourage healthcare institutions and providers to compete on the basis of quality. Policy documents refer to this as 'horizontal supervision'. However, the literature we have reviewed for this report indicates that patients do not as yet behave in this way. They are not guided by performance indicators when making choices. Further investigation is required to ascertain what choice options in healthcare patients really need. But even more important is the question of what this consumer role means for the relationship between healthcare providers and recipients, a relationship which is based on trust. Does this role still leave room for recognising that each party needs the other: healthcare providers with their specialist skills and expertise, patients with their specific needs and priorities, so that they can jointly decide what treatment or care is the most appropriate response to the patient's symptoms? And in broader terms, how will public confidence in healthcare be affected if people are continually reading reports that emphasise failing healthcare providers?

Furthermore, the political principle that 'quality must be measurable' can easily lead to a situation in which the relative importance of different performance indicators is obscured. Injustice and imbalance could result. 'Injustice' where healthcare providers are addressed and judged by outcomes which fail to take sufficient account of contextual factors over which they have no influence, for example the exact make-up of the patient population. 'Imbalance' can result from the choice of indicators that are perhaps insufficiently representative. All the energy and attention might then be brought to bear on improving a measurable aspect of care, without at the same time improving the quality of what underlies it. Another question is what the emphasis on measurability means for other parts of healthcare, such as nursing and personal care, or other aspects such as the way patients are treated by healthcare professionals and how they perceive their healthcare experience, for which it may be harder to develop good performance indicators.

Finally, another important moral question is whether the costs and bureaucracy associated with the public use of performance scores is proportional to the rewards in terms of better quality and accountability. The results of the literature review indicate that this is still unclear. The social experiment which this undoubtedly is requires a cautious, gradual approach combined with ongoing assessment and investigation of the effects.

What next?

The debate on the public use of performance indicators has so far been conducted from firmly entrenched positions, and is often couched more in absolute terms, i.e. that this approach is either entirely rational or complete nonsense, than in examining specific opportunities and risks. This examination is vital if policies in this area are to be developed sensibly. All participants in the debate need to have an open mind, and the discussion must be held against a background of scientific data and ethical analysis. We hope that this report will contribute to the future debate.
It is vital for support to be generated and distrust overcome. This can be achieved by working on two fronts. The Government can help by turning away from imposing external stimuli as the prime, or only, method of improving quality and appealing instead to the intrinsic motivation of professionals, enabling them to express this motivation in their work. It must be made quite clear that performance indicators will be used in such a way that no-one needs to fear being exposed without justification, or suffering professional damage without good reason. Another important condition is avoiding unnecessary bureaucracy.

As far as healthcare providers are concerned, the main challenge is to experience the demand for systematic quality improvement in a different way. Not as something imposed from outside, as a chore to be undertaken to avoid penalties or image problems, but as a core element of professional responsibility. Quality improvement should be an intrinsic part of the healthcare sector: a vital basic skill which professionals at all levels must develop. This aspect must be addressed in training, which is not sufficiently the case at present.

The approach we are arguing for would mean professionals in the medical sector, particularly scientific associations, taking ownership of the initiative. This would take the form not only of developing performance indicators for use in the context of internal quality systems but also in assessing which indicators are suitable for external use.

Further research is needed into the effects and side-effects of public use of performance indicators in the healthcare sector, the effects of reward systems, and patients' need for performance information when making healthcare choices. The representativeness of performance indicators is a key issue as they come to be developed. It is also important to ensure that aspects for which it is more difficult to develop good performance indicators, such as personal attention, the way patients are treated by healthcare professionals and other relationship factors, are not neglected.

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Should blood donors be tested for Variant Creutzfeldt-Jacob disease? (2006)

Variant Creutzfeldt-Jakob disease (vCJD) is one of the prion diseases (disorders that arise from an irreversible mutation in the prion protein). The BSE epidemic in the United Kingdom is generally acknowledged to have been the cause of this disorder. Variant CJD displays a different clinical and pathological picture from the classic form of Creutzfeldt-Jakob disease (CJD) in that young people can also contract the disease and in many patients vCJD initially manifests itself in behavioural changes, which result in a visit to a psychiatrist. The patients usually die after a period of just over one year. A decade after it was first reported, vCJD remains a progressive and invariably fatal disease.

The ability to detect abnormal prion protein in lymphoid tissue from vCJD patients by means of the so-called Western Blot test paves the way for laboratory testing. The British government has commissioned retrospective research on tonsil and appendix tissues removed during operations. Extrapolation of the results of this research suggests that abnormal prion proteins are detectable in 237 per million inhabitants of the United Kingdom. No data of this kind are available for the Netherlands. The prevalence here is presumed to be lower than in the United Kingdom, but how much lower is not known.

It is highly probable that transmission of vCJD via blood transfusions has occurred. In the United Kingdom, two recipients of cellular blood products (derived from a donor who was subsequently to develop vCJD) have died from vCJD. The chances of these deaths being unrelated to the receipt of the blood transfusions are extremely slim. In a third recipient, who died of a different cause, abnormal prion proteins were detected in spleen and lymph nodes.

Transmission via blood transfusion has led to calls for a rapid, non-invasive test based on the detection of abnormal prion protein in the blood (the previously mentioned Western Blot test does not have these characteristics). Various companies and university groups are busy developing just such a test and rapid advances have been made. It is expected that a test suitable for use in a blood bank will be on the market within a few years. The test characteristics are not known at present, nor is it clear what the costs of introducing such a test will be. Nevertheless, there will probably be great pressure to introduce this test in the United Kingdom. The case for and against testing will probably also be debated in France and Ireland in the relatively near future. This issue will also need to be considered in the Netherlands, partly because introduction elsewhere may act as a precedent.

The framework for decision-making in this area will be defined by government's constitutional and internationally enshrined responsibility for the availability and safety of blood supplies. That responsibility is fleshed out in the Blood Supply Act (Wibv). Implementation has been entrusted to the Sanquin Blood Supply Foundation. The basic premise of the Blood Supply Act is that the supply of blood in the Netherlands “must satisfy stringent safety and quality requirements”. The government has repeatedly
emphasised that this does not mean maximum safety, but optimum safety. After all, maximum safety would mean ruling out every possible risk, regardless of the relationship between the health benefit that stands to be achieved and the costs and other disadvantages associated with this measure. The limited financial resources available within the healthcare system are not the only reason why such an approach cannot be justified.

Tests are performed on donors and their blood in order to protect the recipients against bloodborne diseases. In the case of serious, untreatable disorders, however, a dilemma arises. After all, the corollary is then that a positive (i.e. abnormal) test result may have extremely far-reaching consequences for the donor. It is very emotionally distressing to discover that you have an increased risk of developing a serious disease which can neither be treated nor prevented. This information may also have negative implications for the person concerned as far as work and insurability are concerned, or otherwise may lead to exclusion and stigmatisation. This makes testing for such disorders, and therefore also for vCJD, both morally and legally problematic.

Furthermore, if the introduction of a test for vCJD were to result in large numbers of donors being deterred from continuing to give blood, this could jeopardise the maintenance of adequate blood supplies. For various reasons, it is unacceptable – also from a legal standpoint – to test the donor and then not inform him/her of the result. The question therefore arises as to whether it is sensible to test for vCJD if the price to be paid for securing this greater safety would be that insufficient blood is available to meet the needs of patients.

A further significant problem in this connection is the large number of false-positive results that can be anticipated. If prevalence is low, this problem cannot be avoided even by using a relatively specific test. Also to be taken into consideration is the fact that an initial test is probably less discriminatory and that a confirmatory test may not yet be available at first. Besides causing unnecessary anxiety, false-positive results also result in further exclusion of donors. False-negative results, which probably occur far less often, engender unwarranted reassurance in the donor and a lack of certainty in the recipient.

The decision-making over the possible introduction of a test for vCJD will in any case take place under conditions of great scientific uncertainty. Relevant considerations are the question of whether the greater safety for recipients offsets the disadvantages of testing for the donors, the extent to which such a test will, in fact, undermine donor willingness, and the cost-effectiveness of testing for vCJD. Further research – both into attitudes among donors and into the prevalence of abnormal prion proteins in the Netherlands – can only go so far in helping to reduce the continuing uncertainties. The question of what we are to understand by 'optimum' blood safety in this context is still unresolved. This issue is further complicated by the fact that public perception of risk is also shaped by all manner of affective (and consequently less 'rational') factors. Under the Blood Supply Act, the government can decide that blood donors must be tested for vCJD. However, the Sanquin Blood Supply Foundation – the privatised blood supplier – also bears a responsibility of its own. Clearly, concerted policy development is desirable, also because of such aspects as financing and liability.

If it is decided to introduce testing, additional measures will be required in order to minimize undesirable consequences for donors and others. First of all, the donor must be adequately informed about the test for vCJD and its possible implications. Then donors with a positive test result must be offered counselling services. Donors who test positive must be assured of adequate care and protected against forms of stigmatisation and social exclusion. We must assess whether (and under what circumstances) it is desirable to trace and inform the recipients of earlier transfusions with blood from donors who have been found to test positive. For the protection of third parties, steps must be taken to prevent further
transmission of abnormal prion proteins in the course of delivering medical care to donors who test positive.

If the outcome of the decision-making is that a test for vCJD is not introduced in the Netherlands (for the time being, at least) because such a measure would not be consistent with a policy that is geared to optimum safety, or because the negative consequences of its introduction outweigh the positives, then the emphasis will shift from the consequences for the donor to the implications for the recipient. In the event of adverse health effects that could have been avoided by testing for vCJD, Sanquin (and possibly also the government) may be held liable. The precise legal implications in this scenario require closer consideration. From a moral perspective, consideration also needs to be given to the possibility of compensating people who contract vCJD as a result of the decision not to test donors.

It is also possible that calls may be made for the introduction of a test for vCJD in other areas of medicine, in order to protect patients and care providers against the risk of transmission. Two such areas are surgery (especially neurosurgery) and transplantation medicine. Here too, timely consideration of the pros and cons of a test for vCJD is desirable. This is primarily a matter for the relevant professional groups and patients’ organisations to consider.

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