[The translation below has not been authorized by (all) authors.]

The expression of objection by incapacitated (psycho)geriatric patients in the context of the WMO*

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1 Objection may generally be defined as the verbal and/or non-verbal expression of resistance or opposition to procedures (to be) performed on or with the person in question. On the basis of this broad definition, objection may be regarded as a form of behaviour. In the case of a legally competent individual, the interpretation of such behaviour almost never presents (significant) problems. This is not the case, however, in the case of an subject incapacitated to participate in the formulation of decisions concerning procedures to be performed on or with him or her in the context of medical research. In such cases, third parties must always determine whether an observed form of behaviour should be interpreted as objection. If it is decided that a form of behaviour does constitute objection, the procedures in question may not be performed on or with the individual in question.

2 Determining whether behaviour should be interpreted as an expression of objection requires familiarity with the (prospective) subject's habits, behavioural norms, preferences and dislikes. In the case of a person whose incapacitation is the result of illness or disorder, his or her patterns of behaviour may differ significantly from those seen prior to the onset of morbidity. This is particularly so where a condition such as dementia, which typically involves multiple personality changes, is concerned. The starting point for the assessment of objection must always be the behaviour pattern of the present person.

3 In case of an incapacitated subject, a representative must make decisions on his or her behalf. The WMO stipulates who is entitled to represent an incapacitated patient in matters relating to participation in medical research. The representative's role goes beyond merely giving or withholding consent; he or she should be actively involved in deciding whether the patient's behaviour must be interpreted as an expression of objection to participation. When acting on the patient's behalf, a representative should be guided by the following:

- any written advance directive of living will the patient may previously have made, which provide a basis for determining the patient's wishes with regard to the matter under consideration;
- a reconstruction of the patient's wishes.

The representative's role in the assessment of objection should also be consistent with the Medical Treatment Contracts Act (WGBO), which imposes on a representative a duty of conscientious representation. This can be significant in cases where a representative's involvement is peripheral or where a representative cannot be considered familiar with the patient's normal behaviour.

4 The assessment of behaviour should in principle be a multidisciplinary process. The precondition for acting as an assessor is familiarity with the patient. It therefore follows that, in addition to the physician in charge of the case and the patient's representative, nurses can make an important contribution to the process, because of their close day-to-day

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involvement with the patient. It can also be advisable to seek the views of other professionals who are closely involved with the patient (e.g. social workers and/or psychologist). Finally, other family members and relatives who are not qualified to act as the patient's formal representatives can sometimes provide valuable information as well.

5 Examples of behaviour that in may generally be regarded as expressions of objection include:

- verbal utterances such as: 'no', 'don't do that', 'I don't want to', 'you're hurting me';
- non-verbal expressions of pain or fear, tension, walking away from the investigator, explicit physically aversive behaviour such as pushing away, hitting out, kicking, keeping the mouth tightly shut, turning the head away, groaning, moaning, and weeping.

Any incapacitated patient is liable to exhibit such forms of behaviour. The significance of such behaviour will vary from one individual to another, but should be apparent to those that know the patient well. Such behaviour must be distinguished from any uncertainty or reserve that is normal for the patient when confronted with new and/or unsettling situations (e.g. when showering, swimming, giving blood samples). Behaviour should be interpreted as objection only if it clearly differs in nature or degree from that typically displayed by the subject in situations not encountered on an everyday basis. However, if a patient is strongly resistant to everyday care procedures, it is advisable not to involve him or her in any proposed research. Furthermore, if the prospective subject's normal behaviour is such that he or she may be expected to resist participation (anticipated behaviour), exclusion is advisable.

6 If there is doubt as to whether a patient's behaviour should be interpreted as an expression of objection, or if the assessors disagree as to the interpretation of the patient's behaviour, consideration may be given to involving the patient in the research for an agreed pilot period, during the course of which the assessors seek to obtain a better understanding of (the significance of) the patient's behaviour, by reference to clearly defined criteria. If doubt or disagreement remains, the patient in question should not participate or continue to participate in the research.

7 A subject's (verbal and non-verbal) responses to procedures carried out in the context of research should be noted both in his or her medical record and in the research file. Furthermore, with a view to facilitate subsequent review, a record should also be kept of the conclusions reached regarding the subject's behaviour, the grounds for these conclusions and the names of the people making the assessment.

8 Assessment of a (prospective) subject's behaviour should not be a one-off exercise conducted at the commencement of the research, but should continue through all phases of the research. If the subject's behaviour changes in the course of the research, this may warrant the discontinuation of his or her participation. It therefore follows that carers or representatives who are familiar with the subject's normal patterns of behaviour should be involved not only at the start of the study, but also while it is in practical progress. The investigators accordingly have a responsibility to make arrangements for the involvement of such individuals that are practical in the context of the research, and to detail these arrangements in the research protocol.

9 The research protocol for a study that is to involve incapacitated subjects should explicitly state what is to be done if subjects object to (continued) participation. The medical ethics review committee responsible for the review of such a research protocol should satisfy itself that this requirement has been complied with.

Explanatory notes

Re point 1 Procedures performed in the context of the research include any observations, interviews, questionnaires and such like.

Re point 2 The information provided serves as a reference framework for the assessment of a (prospective) subject's behaviour during medical research. Anyone making such behavioural assessments should be familiar with and have a clear understanding of this reference framework. This implies that those who make judgements regarding the significance of a (potential) subject's behaviour must know the individual in question well. The reference period with which behavioural signals are compared will differ from one individual or group to another, depending on the nature, cause and duration of the incapacitated state.
The phrase 'the present person' is used for consistency with the terminology of the directive 'Medical decision-making concerning patients with dementia' issued by the Dutch Association of Nursing Home Physicians (Utrecht: NVVA, 1997). This means that assessors should not concern themselves with the views and attitudes of the person prior to the onset of morbidity (e.g. before he or she developed dementia), but should compare behaviour observed in the context of the research with that familiar to carers in the period immediately prior to the research, taking account of any changes in the patient's preferences and dislikes associated with his or her (chronic) condition. Where patients whose incapacitation is more or less 'acute' (e.g. those with a delirium) are concerned, this can be difficult to do. In such cases, assessors will need to compare behaviour observed in the context of the research with that habitually displayed prior to the acute disturbance of the patient's competence.

Re point 3 The representative's responsibilities go beyond giving consent, in his/her capacity as a suitably qualified third party, for the subject's participation in the research. The representative also shares responsibility for assessing whether behaviour constitutes objection and deciding whether the subject's behaviour warrants discontinuation of his or her participation. It is, however, necessary to take account of the possibility that a subject's legal representative does not know the subject and/or understand the nature of the care provided sufficiently well to discharge these responsibilities adequately. The provisions of the WMO regarding representation differ from those of the WGBO and BOPZ, insofar as the WMO allows representation of the subject only by his or her legal representative, or, failing that, a proxy with written authority from the subject, or the subject's spouse or other life-companion. Within the context of the WMO, therefore, a child cannot act as a subject's representative, unless he or she has the subject's written authorisation.

Code of conduct concerning the assessment of expressions of objection by incapacitated (psycho)geriatric patients in the context of medical research

Background

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Following an extended period under development, and seven years after publication of the original bill, the *Medical Research Involving Human Subjects Act* (WMO) came into full effect on 1 December 1999.[1] The act regulates the review of medical research. It prohibits medical research that involves as subjects people who are not competent to decide whether it is in their interests to participate or people who are not in a position to decide freely whether to participate, except where certain criteria are met. The act also stipulates that participation must be based on informed consent,

[1] Act of 26 February 1998, regulating medical research involving human subjects (Medical Research Involving Human Subjects Act), Bulletin of Acts, Orders and Decrees 1998: 161. The Hague: SDU, 1998

requires the appointment of an independent physician to advise subjects and makes certain provisions regarding liability and insurance. Rules are laid down concerning the action to be taken if the research proves to have unexpected adverse consequences for the subject. In addition, the WMO contains provisions designed to protect subjects' privacy. One of the topics that has generated most public debate has been the acceptability and regulation of non-therapeutic scientific research involving human subjects who are not themselves competent to consent to participation (i.e. incapacitated subjects).[2] When the original bill came before the Lower House in 1993, the provisions regarding non-therapeutic research with legally incompetent subjects met with such a critical and unacceptable response that the government considered prohibiting such research altogether – a move which would have had far-reaching consequences. This prompted twelve medical and research organisations to publish a joint statement drawing attention to, amongst other things, the importance of enabling non-therapeutic research with incapacitated subjects to continue.[3] So it was that in 1994 an independent advisory committee was set up to look into the matter. The recommendations made by the Meijers Committee, as it became known, were largely incorporated into the final version of the act.[4]

A number of issues are not addressed by the act because they are difficult to regulate by statutory means. These issues include the assessment of legal competence, how the requirement concerning informed consent can be met in relation to incapacitated subjects to give such consent, and the interpretation of possible expressions of objection.[5,6] The increasing interest that the professional associations have shown in clarifying these matters and, where possible, formulating codes of conduct can facilitate practical implementation of the WMO in an appropriate manner.

In line with the Meijers Committee's recommendations, the WMO stipulates that if an incapacitated subject objects to participation in (therapeutic or non-therapeutic) research, he or she cannot be forced to participate. Specifically, section 4, subsection 2, of the WMO states: '*If a subject participating in …medical research objects to receiving a particular treatment or being required to behave in a particular way, the research shall not proceed with that subject.*' In the explanatory notes and responses accompanying the further amended bill of September 1997, it says that '*when considering whether, in a specific instance, a subject's behaviour constitutes objection, allowance should be made for the fact that an incapacitated subject is generally apt to respond with greater reserve than an average adult to events that he or she is unused to in everyday life.*' This statement is consistent with the Meijers Committee report, which suggested that the behaviour of an incapacitated subject in medical research should be deemed to constitute objection only if it was clearly inconsistent with normal behaviour patterns within people of the category concerned.

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[2] Dillmann RJM. Medisch-wetenschappelijk onderzoek met wilsonbekwame patiënten. Kunnen we tevreden zijn met de Nota van Wijziging betreffende de Wet Experimenten? [Medical research with incapacitated patients. Can we be satisfied with the proposed amendments to the Experimentation Act?] Medisch Contact [Medical Contact] 1996; 51; 514-6.

[3] Dillmann RJM, Kastelein WK. Niet-therapeutisch wetenschappelijk onderzoek met wilsonbekwame patiënten. Een gezamenlijk standpunt van Nederlandse medisch-wetenschappelijke organisaties [Non-therapeutic medical research with legally incompetent patients. A joint statement of principles by the Netherlands' medical research organisations]. Nederlands Tijdschrift Geneeskunde [Netherlands Journal of Medicine] 1994; 138: 1676-80

[4] Meijers Committee. Advies inzake regeling van medisch-wetenschappelijk onderzoek met wilsonbekwamen [The regulation of medical research with incapacitated subjects]. The Hague, June 1995

[5] Olde Rikkert MGM, Verweij MF, Hoefnagels WHL. Informed consent en beslisvaardigheid bij medisch-wetenschappelijk onderzoek [Informed consent and the ability to make decisions in the context of medical research]. Tijdschrift Gerontologische Geriatrie [Journal of Gerontological Geriatrics] 1995; 26: 152-62

[6] Hertogh CMPM. De Wet medisch-wetenschappelijk onderzoek met mensen en de moraal van vader Cats [The Medical Research Involving Human Subjects Act and the moral of father Cats. Tijdschrift Gerontologische Geriatrie [Journal of Gerontological Geriatrics] 1998; 29: 50-1

Hence, the Meijers Committee introduced a significant distinction between 'objection' and the level of reticence or uncertainty normal for patients of the category in question when confronted by procedures or events unfamiliar to them from their daily lives. No such distinction is made in, for example, the BOPZ. The concept of 'objection' has thus been given a more subtle definition, which is more consistent with the moral intuition of care providers.

Consultation group

With a view to facilitating practical implementation of the WMO's stipulation (section 4, subsection 2) that a subject who expresses an objection to participation in medical research cannot be made to participate, and at the explicit request of the Lower House, following the plenary debate in the house in September 1997, the Minister of Health asked the Netherlands Association for Paediatric Medicine, the Netherlands Association of Physicians Caring for the Mentally Disabled and the Dutch Association of Nursing Home Physicians (NVVA) to develop a code of conduct for the assessment of expressions of objection by people not competent to consent to participation in medical research. In response to this request, the Consultation Group on Objection in the Context of Medical Research involving Incapacitated Subjects was formed in 1998, with representatives from the above-mentioned associations and policy officials from the Ministry of Justice and the Ministry of Health, Welfare and Sports (VWS). The ministry representatives in particular were keen that a common code of conduct should be produced. However, the diversity of the categories of patients involved was such that this was ultimately deemed impractical. Nevertheless, the three separate codes that were developed are broadly consistent with one another and incorporate the following common themes:

1 The assessment of a (prospective) subject's behaviour requires familiarity with the person in question; this implies that care staff and relatives have an important role to play;
2 Behaviour should be assessed by reference to a) the (prospective) subject's 'normal' behaviour pattern and b) the type of reticent behaviour normal for people in the group to which the (prospective) subject belongs when confronted by things and events not encountered in everyday life;
3 Written records should be kept noting the (prospective) subject's responses to the research and the interpretation of them;
4 The protocol for a study that is to involve incapacitated subjects should explicitly state what is to be done if subjects object to (continued) participation. The medical ethics review committee responsible for the review of such a protocol should satisfy itself that this requirement has been complied with.

   At the instigation of the NVVA representatives, it was decided to invite the Psychiatry Association (VvP) and the Netherlands Association for Geriatrics (NVvG) to join the consultation group with a view to assisting with the development of a code of conduct covering elderly people who are no longer legally competent. Unfortunately, the invitation was not taken up by the VvP. Consultation between the NVVA and the NVvG resulted in development of the code of conduct presented in this issue of the journal, which has been approved by the boards of the NVVA and the two associations recently formed by the division of the NVvG, namely the Dutch Geriatrics Society and the Netherlands Association for Social Geriatrics.

Guideline

The code of conduct serves as a guideline for investigators seeking to carry out medical research using incapacitated (psycho)geriatric patients as subjects, and for medical ethics review committees which have to review the protocols for such research. Naturally, a proper procedure for assessing possible expressions of objection is only one of the requirements that must be met for medical research with patients from this group to be acceptable. The WMO imposes numerous conditions, particularly in relation to research with incapacitated subjects. To protect such individuals, the WMO prohibits their involvement in medical research 'unless either the research can be directly beneficial to the subject, or the research cannot be conducted without the participation of subjects

of the category in question and the risks associated with participation are negligible and the burden minimal' (section 4, subsection 1). Thus, instead of giving conditional permission for medical research involving subjects who are not competent to make decisions regarding participation, the act imposes a prohibition with exceptions.

Approval

Research with incapacitated subjects requires the approval of the new Central Committee on Research Involving Human Subjects (CCMO) if the condition of the subjects is to be deliberately altered and participation is not directly beneficial to them (section 2, subsection 2, of the WMO). Other forms of research can be reviewed by medical ethics review committees accredited by the CCMO. It is anticipated that, in the context of the various forms of research protocol review, the therapeutic value of a proposed study will often have to be examined very carefully. However, the act again gives little guidance as to how this should be done.

Once a study has been approved by the CCMO or an accredited medical ethics review committee, written proxy consent must be obtained for each subject's participation from his or her legal representative, proxy with written authority, spouse or other life-companion. The representation rules laid down by the WMO differ from those of the WGBO, insofar as a child cannot act as a subject's representative, unless he or she has the subject's written authorisation. In practice, this will have restrictive implications for the performance of research with psychogeriatric patients, as has been pointed out elsewhere.[7] The act also stipulates that the subject must be informed about what is proposed in a way that takes account of his or her intellectual capabilities.[8] When research is carried out using vulnerable and (partially) dependent people of this kind, any behavioural changes need to be very carefully assessed. Where it is clear that a (prospective) suspect objects to participation, research with the person in question should be discontinued. An investigator who is obliged to curtail research in this way has the consolation of knowing that such an approach assures not only the welfare of the subject, but also the reliability of the study. The reason being that both somatic and psychological functions can be seriously disturbed by disquiet on the part of the subject; hence, the inclusion of subjects who object to participation can distort research findings.

The code of conduct concerning the assessment of expressions of objection in the context of the WMO clarifies one of the problematic concepts introduced by the recent healthcare-related legislation. The increasing interest in the interpretation of such concepts (including also capacitation and objection in the context of the BOPZ) is to be encouraged.[9] If such interest leads to the formulation of codes of conduct or guidelines, practical implementation of the legislation will be facilitated significantly. It would also be advantageous to explore the scope for greater alignment of the definitions given to concepts such as objection and legal competence in various acts (BOPZ, WGBO, WMO).

By the publication of the code of conduct, the three associations hope to secure two objectives. First and foremost, the intention is to afford the vulnerable group of incapacitated geriatric patients adequate protection against the risks associated with participation in research for which they are no longer able to give explicit consent. At the same time, the wish is to assist those organising and reviewing medical research, so that vulnerable geriatric patients can ultimately benefit from scientific progress in the fields of diagnosis, treatment and care.

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[7] Tijdschrift Gerontologische Geriatrie [Journal of Gerontological Geriatrics] 1999, no. 30, pp 247-8

[8] Roscam Abbing HDC. Onbekwaamheid, medisch handelen en belangen van derden: waar liggen de grenzen? [Incapacitation, medical procedures and third-party interests: where do the boundaries lie?] Nederlands Tijdschrift Geneeskunde [Netherlands Journal of Medicine] 1995; 139: 2746-9

[9] Grouwenberg BM, Jonker C, Smit JH, Schmand B. Beoordeling van wilsonbekwaamheid bij ouderen met dementie. Ontwikkeling van een methode [The assessment of incapacitation in elderly people with dementia. The development of a method]. Amsterdam: Free University, 1997