Medical Research involving Human Subjects Act

Country: Netherlands
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Health Policy Issues: Pharmaceutical Policy, Quality Improvement, Responsiveness

Current Process Stages

1. Abstract

The Medical Research involving Human Subjects Act (WMOM) offers legal protection to research subjects by setting out a number of substantive norms and procedural rules. The WMOM came into effect on 1 December 1999. An independent evaluation study completed in 2004 shows that in practice the WMOM by and large functions properly. However, there is still room for improvements.

2. Purpose of health policy or idea

The main purpose of the WMOM is to protect research subjects (patients and volunteers) against the risks and burdens of biomedical research involving human subjects without unnecessarily hampering the progress of medical-scientific research. The WMOM applies to all biomedical research ‘in which persons are subjected to acts or are required to behave in a certain way’. This includes pharmaceutical research (and to implement Directive 2001/20/EG there are some specific rules for this kind of research), but it will be clear from the definition that the law has a broader scope. Furthermore, the WMOM pertains not only to intervention research, but also to some types of observational studies.

Research projects should be carried out in accordance with a research protocol which should contain a detailed description of the project. This protocol needs the approval of an acknowledged review board that is multidisciplinary composed. The review process includes a number of aspects of the protocol, such as the necessity of the research, its methodology, the risk-benefit ratio and the researcher's expertise. The review board will also ascertain whether or not the rules for informed consent have been complied with. Finally, the research project may only be carried out if insurance covering the test's subject's death or injury caused by the research has been taken out.

In case of multicenter research, the approval of one review board suffices. However, the board of management of every participating centre has to certify that the proper implementation of the project is feasible within its centre.

The review boards need the acknowledgement of the Central Committee on Research involving Human Subjects. At this moment, 33 review boards have been acknowledged. Certain types of research, for instance therapeutic genetic research, are reviewed by the Central Committee itself. In addition, the Central Committee supervises the activities of the review boards and can draw up guidelines. Finally, an appeal can be lodged with the Central Committee against a judgment passed by the review board. As such, the Central Committee is unique in the world.
Main objectives

- Main objective of the WMOM is the protection of research subjects against the risks and burdens of biomedical research without unnecessarily hampering the progress of medical science
- Biomedical research should comply with legal rules guaranteeing the quality and acceptability of the project and the informed consent of the research subject
- Review of research protocols is carried out by acknowledged, multidisciplinary composed review boards
- A central committee acts as an independent coordinating body for the review boards

Type of incentives

Non-financial incentives

Groups affected

Pharmaceutical industry, Research subjects, Biomedical researchers, (Academic) hospitals

3. Characteristics of this policy

<table>
<thead>
<tr>
<th>Degree of Innovation</th>
<th>traditional</th>
<th>innovative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Degree of Controversy</td>
<td>consensual</td>
<td>highly controversial</td>
</tr>
<tr>
<td>Structural or Systemic Impact</td>
<td>marginal</td>
<td>fundamental</td>
</tr>
<tr>
<td>Public Visibility</td>
<td>very low</td>
<td>very high</td>
</tr>
<tr>
<td>Transferability</td>
<td>strongly system-dependent</td>
<td>system-neutral</td>
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</tbody>
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The most important innovative aspects are:

- the scope of the WMOM extends to all biomedical research involving test subjects, not only to pharmaceutical research;
- there are balanced rules for the permissibility of non-therapeutic research with children and incapacitated adults (which rules served as a model for the Convention on Human Rights and Biomedicine of the Council of Europe);
- The sponsor of the research project is obliged to take out a so-called test subject insurance, which is not a liability insurance but a personal accident insurance;
- the fact that the ethical review process of research protocols is placed in a legal framework;
- the unique position of the Central Committee and its important role in practice.
4. Political and economic background

Since the 1970s, following initiatives in the United States, Institutional Review Boards for research involving human subjects have developed within hospitals on the basis of self-regulation. In the 1980s, as a part of a broader movement to enact patient rights, it was deemed necessary to lay down by law the substantive and procedural framework for the review of research protocols. At the time the WMOM was enacted there was no EU legislation to comply with. EU-Directive 2001/20/EG is implemented by way of amending the WMOM.

5. Purpose and process analysis

Origins of health policy idea

The WMOM was built on a long standing practice of ethical review of medical research projects. As such the WMOM has laid down by law the widely recognized ethical norms for biomedical research and an even widely recognized institutional framework for reassuring that these norms are observed in practice. However, the Act has also introduced some new elements. At the parliamentary process one of the main topics of discussion was the permissibility of non-therapeutic research with children and incapacitated adults. It was voiced that such research should be abandoned totally, but as a consequence certain types of research would no longer be possible then. According to the WMOM this kind of research may be carried out if the risks associated with participation are negligible and the burden for the research subject is minimal. Another important element of the WMOM is the introduction of the Central Committee. This Committee has greatly improved the quality of the review process. Every review board has to consider at least ten research protocols per year; otherwise the acknowledgement will be withdrawn. As a result of this, the number of review boards has diminished from about 80 to 33. Another innovation of the WMOM is that the review boards are no longer private institutions. They should be considered as administrative bodies and as such they have to apply the rules of administrative law (with regard to the decision period, open government and so on).

Initiators of idea/main actors

- Government: In 1982 a committee on patient? roofs rights chaired by professor Leenen, a well known health lawyer, advised the government to enact patient? s rights in the context of biomedical research. One year later the government adopted this advice.

- Scientific Community

- Political Parties

Stakeholder positions

The need for a legal framework for the protection of the rights of research subjects was generally felt. Furthermore, Article 10 and 11 of the Dutch Constitution of 1983 provide for the right to privacy and the right to physical integrity. With regard to biomedical research these constitutional rights required more detailed elaboration.

Actors and positions

Description of actors and their positions

Government
Influences in policy making and legislation

A first draft of a bill on medical experiments, made public in 1985, was rejected because a license was required for conducting an experiment which ran counter to the deregulation policy of the government. A second draft, made public in 1987, was also rejected. In 1992 a Bill on medical experiments was submitted to Parliament. There was a heated discussion in- and outside Parliament as to the permissibility of non-therapeutic research with children and incapacitated adults. A special commission chaired by Judge Meijers formulated the conditions under which this kind of research might be acceptable. Thus the dispute was settled. The name of the bill was changed in the Medical Research involving Human Subjects Bill, in order to take away doubts about the scope of the bill. In 1997 the bill passed the Lower House by general consent. In 1998 the bill passed the Upper House even without voting. In 1999 the Medical Research involving Human Subjects entered into force.

Legislative outcome

success

Aactors and influence

Description of actors and their influence

Government
Government very strong strongly opposed

Scientific Community
Scientific Community very strong strongly opposed

Political Parties
Political Parties very strong strongly opposed

Positions and Influences at a glance

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Monitoring and evaluation

According to Article 37 WMOM the Minister of Health, Welfare and Sports has to send to Parliament a report on the effectiveness and the effects of the Act in practice within four years after the entry into force of the Act, and subsequently every five years. The first report, drawn up by an independent research team, was completed at the end of 2004.

Review mechanisms

Final evaluation (external)

Dimensions of evaluation

Structure, Process

Results of evaluation

Two surveys were conducted, one of review committees and one of researchers. According to the review committees and the researchers the level of protection of research subjects remained the same or has even become higher
since the introduction of the WMOM. According to the researchers bureaucracy has increased. Furthermore, they are dissatisfied with the length of the review process and they are worried about the workload and the costs which are involved with it. Whether or not medical research is hampered by these developments remains unclear.

In 2003 1700 research protocols were reviewed. The case load of individual members of the review committees varies from 2 hours to 160 hours per month, on average 14 hours per month. The review committees are sometimes in doubt whether or not a particular research project falls within the scope of the WMOM. Some committees also review non-WMOM medical research protocols, others don’t. According to the review committees in 81% of the cases the review process is completed within the legal decision period of 8 weeks. Pursuant to a directive of the Central Committee, in case of a multicenter trial the approval of only one review committee is required. For the review committees of the other participating centres it is sometimes hard to accept that they are not allowed to pass their own judgment as was the case before the introduction of the WMOM.

Research subjects should be informed in writing and during the review process much attention is paid to the informed consent procedure. However, simple health educational techniques are not applied systematically. Consequently, it remains unclear whether or not research subjects can really make an informed choice.

The Central Committee has grown into a solid and professional organisation. According to the review committees the quality of the advices of the Central Committee and its readiness to answer questions are excellent. The Central Committee has added greatly to improving the quality of review process. It has reduced the number of review committees drastically. It has also clarified some legal indistinctnesses. Furthermore, it has conducted in-depth investigations into the quality of the review process with regard to non-therapeutic research with children and incapacitated adults.

6. Expected outcome

By and large, the WMOM seems to have achieved its objectives, i.e. protecting research subjects without
unnecessarily hampering the progress of biomedical research. It should be noted, however, that in the review process emphasis is placed on the review of research protocols. More attention should be paid to the phase of implementation of the research protocol.

### Quality of Health Care Services
- marginal
- fundamental

### Level of Equity
- system less equitable
- system more equitable

### Cost Efficiency
- very low
- very high

Evidence-based medicine can only progress on the basis of sound scientific research which is carried out with respect for human rights.

## 7. References

### Sources of Information

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- The Central Committee on Research Involving Human Subjects Website: www.ccmo.nl

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