Definition of medical research

Introduction

The CCMO secretariat is regularly asked whether a study needs to be reviewed by an accredited medical research ethics committee. The first question that needs answering is whether the study is considered medical research. If this is not the case, no ethical review is required.

Definition of medical research

Medical Research Involving Human Subjects Act (WMO) and the Meijers Committee

The Medical Research Involving Human Subjects Act (WMO) gives no clear definition. The law defines 'scientific research' as: 'medical research, part of which involves subjecting persons to actions or imposing certain behaviours upon them'. The explanatory memorandum[1] also speaks of 'research with the goal of developing or improving diagnostic methods and curative treatments'.

During the creation of the Medical Research Involving Human Subjects Act (WMO) (known at the time as the *medical experiments bill*), a committee of experts (the so-called Meijers committee) was appointed to advise the government on the usefulness and acceptability of medical research with underage subjects and individuals unable to give informed consent[2]. This committee proposed replacing the term 'medical experiments' with 'medical research'. The primary reason for this proposed change was that the term 'experiment' is primarily used for interventional studies and not for observational research in the world of science. The term 'medical experiment' also had negative connotations for many people. The Meijers Committee writes the following on what 'medical research' should be understood to encompass:

> 'A key characteristic of scientific research is that systematic observations and reasoning is used to attempt to reach conclusions with more general applicability. The primary objective is knowledge. In medical research, this

[1] Parliamentary Papers II 1991/92. 22 588, no 3, p. 7

[2] Meijers LCM: Reccomendations regarding regulation of medical reseach with individuals unable to provide informed consent. Ministry of Sports, Welfare and Public Health, Rijswijk, 1995.

knowledge largely benefits patients in the long or short term. Scientific research examining whether a new therapy is better than the old one does not solely aim to improve the health of individual study participants. Answering the question of whether this therapy can better help a specific group of patients or has fewer side-effects is the underlying study goal. The difference between medical treatment and scientific research is therefore clear. Medical treatment is solely focused on the welfare of the individual patient, while scientific research encompasses actions that are not, or not solely in the interest of the involved party.'

Medical research, therefore, must deliver general knowledge that may eventually benefit patients, but not solely the individual participant in the study. This description focuses primarily on the boundaries of (potentially experimental) treatment of individual patients.

In her response to the Medical Research Involving Human Subjects Act (WMO)[3] assessment, the State Secretary stated that the commentary on the WMO leads to the conclusion that the Act applies to 'research involving human subjects having to do with health and disease'.

Medical Research Council

Another definition of medical research is given by the Medical Research Council of Great Britain[4].

MRC definition of clinical research

The MRC defines clinical research as research based primarily on patients or ex-patients and designed to answer a question about disease (aetiology, concomitants, diagnosis, prevention, outcome or treatment). In addition to direct clinical examination, it includes the study of blood, biopsy material or post-mortem tissue deriving from the individuals concerned and of normal subjects where such study relates to a disease process being investigated. The definition includes clinical trials, and of course much other work on the clinical characterisation of disease or ill health.

More specifically, this means that research defined as clinical should encompass at least one of the following categories:

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[3] Letter from the State Secretary to the Chairman of the Second Chamber, reference IBE/E/2605085

[4] http://www.mrc.ac.uk/index/current-research/current-clinical_research/current-clinical_research_definition.htm

Human participation: studies which require face-to-face contact with patients and/or healthy human participants and may involve use of patient records as a concomitant e.g., a clinical trial

Records based studies: studies which require access to personal data on health or lifestyle without involving face-to-face contact with any people e.g., epidemiological studies, health economic studies, public health interventions, health services research and meta-analyses – information may be obtained by telephone, postal questionnaires/surveys or electronic/manual data retrieval.

Clinical samples: studies which involve laboratory studies on human material which are specifically designed to understand or treat a disease/disorder. However, basic biomedical research of remote relevance to a disease/disorder, such as the use of immortalised human cell lines in model biological systems, is excluded.

Technology development for clinical use: development or adaptation of technologies for diagnosis or therapy, e.g., instrument development for diagnostic or surgical use; development of new techniques, such as photodynamic therapy, for clinical use.

This definition focuses more on the boundaries between medical and other scientific research.

Proposal

Based on these two definitions, we may be able to create a useful description. Below is a proposal.

Medical research is research that aims to answer a question in the field of disease and health (aetiology, pathogenesis, concomitants, diagnosis, prevention, prognosis or treatment of disease) through the systematic collection and analysis of data. *The study aims to contribute to medical knowledge that also applies to populations other than the study population itself.*

This definition provides a better framework than the current Medical Research Involving Human Subjects Act (WMO) and is consistent with the Explanatory Memorandum and the Meijers Committee report. However, this definition also fails to abolish a grey area. A better definition within the WMO remains desirable.

Boundaries

In some cases, it is not immediately clear whether the research question relates to medical science. A number of such cases are discussed below.

1. *Behavioural research*
   In behavioural research, participating subjects are often subjected to actions or are required to follow certain behaviours. Sometimes the research question relates to the medical sciences (psychiatry, physiological effects), such that the WMO applies and ethical assessment is required, and sometimes it does not. However, the level of protection provided to test subjects should be comparable. This is why the possibilities for creating a review framework for behavioural research are currently being examined.
2. *Exposure studies*
   In her response to the Medical Research Involving Human Subjects Act (WMO) assessment, the State Secretary addressed the 2004 warning from the Centre for Ethics and Health, which addressed research in which test subjects are exposed to certain substances. *In the opinion of the State Secretary, this is not covered by the WMO if the research is related to the effectiveness of, for example, cosmetics or food/dietary supplements. Research examining whether exposure is associated with health risks, including studies of pesticide toxicity, for example, is covered by the WMO. However, the CCMO is of the opinion that research into the efficacy of foods/dietary supplements should also be covered by the WMO if the desired effect of the food/dietary supplement is related to health. The State Secretary is of the opinion that assessment of exposure studies requires toxicological expertise.*
3. *Quality studies*
   Many institutions, prior to switching to a new instrument or technique, first compare the old and new techniques, for example in terms of cost effectiveness. If such comparisons are not designed to obtain generally applicable medical knowledge, but only serve local purposes (to switch or not), the study is not considered medical research.

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