ERASMUS MC

Report

Follow-up Investigative Committee Academic Integrity 2013

July 25, 2014

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Abbreviations

ACCF:	American College of Cardiology
AHC:	American Heart Association
AMC	Academic Medical Centre, Amsterdam
CBS:	Statistics Netherlands (Netherlands Central Bureau of Statistics)
CRF:	Case Record Form
DECREASE:	Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echo
DSE:	Dobutamine Stress Echo
ECG:	Electrocardiogram
ECHO:	Echocardiogram
Erasmus MC:	Erasmus University Medical Centre
GBA:	Local government population register
KNAW:	Royal Netherlands Academy of Arts and Sciences
LUMC:	Leiden University Medical Centre
METC:	Medical and Ethical Review Committee
NEJM:	New England Journal of Medicine
QRS:	Q, R and S designate three sequential components of an ECG
TASC II:	Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease
WMO:	Medical Research involving Human Subjects Act
ZIS:	Hospital Information System

1. Introduction

1.1. The Committee's terms of reference

On 5 February 2013, the Board of Erasmus MC decided to establish the Follow-up Investigative Committee (Academic Integrity) of 2013, referred to below as "the Committee."

The Committee is the third committee to study possible breaches of academic integrity in publications by Dr D. Poldermans. To explain the background of the formation of this third Committee, we present two conclusions from the two previous committees:

1. "The Investigative Committee for Academic Integrity"

Established: 28 July 2011 Report: 8 November 2011 [1] This Committee concluded that breaches of academic integrity occurred in at least three research projects for which Dr Poldermans was responsible. One of its recommendations was to conduct a more detailed study of some projects that this Committee had been unable to examine within the time available. This recommendation led the Board to establish a second committee (see following point).

2. The Follow-up Investigation Committee of 2012

Established: 1 January 2012 Report: September 2012 [2]

This Committee found that, in addition to the instances identified by the first Committee, breaches of academic integrity had occurred in at least three other research projects for which Dr Poldermans had been responsible. One of its recommendations was that further investigation of Dr Poldermans' publications would be indicated only if compelling new scientific or societal arguments arise in relation to specific components of his oeuvre.

In the autumn of 2012, compelling societal arguments did indeed arise in the scientific community, especially within the Royal Netherlands Academy of Arts and Sciences (KNAW), and Erasmus University was urged to screen the complete work of Dr Poldermans for indications of breaches of academic integrity. The Rector Magnificus agreed to these requests, and decided to ask Erasmus MC to conduct this investigation. This led to the establishment of the present committee.

The Committee has been charged (see Appendix 1) with studying all publications in which Dr Poldermans is named as author or co-author, and to select from them the publications reporting on research conducted by Dr Poldermans himself or under his immediate direction.

The Committee was asked to investigate as thoroughly as possible whether there were indications that academic integrity was breached during the preparation of these publications. The Committee's terms of reference specified that priority should be given to frequently cited publications and to those that had contributed to the formulation of medical guidelines. The Committee was also asked, where possible, to use the forensic statistical methods developed for detecting scientific fraud in published data.

The task facing this Committee was distinct from that facing the two previous committees, whose investigation focused on ascertaining whether academic misconduct could be excluded in a limited number of publications for which there were specific indications that academic integrity may have been breached. To establish that scientific misconduct had occurred, those committees examined these specific indications in detail, case by case, for example by interviewing those involved. In contrast, the present Committee was established to identify indications of scientific misconduct in an extensive body of scientific publications. As of April 1, 2013, PubMed listed 495 publications for which Dr D. Poldermans was an author or co-author. This task required different procedures (see Section 1.2).

The Committee had the following members:

- Dr J.M.W. Hazes, Professor of Rheumatology, Erasmus MC
- Dr P.J. van der Maas, Emeritus Professor of Social Health Care, Erasmus MC (Chair), until July 1, 2014
- Dr R.J.G. Peters, Professor of Cardiology, AMC
- Dr F.R. Rosendaal, Professor of Clinical Epidemiology, LUMC

Administrative support was provided by Dr R.E. Juttmann, Department of Research Policy, Erasmus MC. To complete the Committee's job from July 1, 2014, Dr P.J. Koudstaal, Professor of Neurology, Erasmus MC, took over the tasks from Professor Van der Maas.

The Committee used the services of external experts for the technical aspects of its investigations. It began work on February 25, 2013, and met eight times.

1.2. Procedure

In order of their publication date, each of the 495 publications in Dr Poldermans' oeuvre was assigned a unique identification number. The Committee then examined all the publications relating to studies based on original data that had been carried out either by Dr Poldermans himself (with Dr Poldermans as first author) or under his immediate direction (with Dr Poldermans as penultimate or last author, and one of his PhD candidates as the first author). Review articles, publications on the design of a planned study, commentaries and related publications were not considered. After this selection, 247 of the 495 publications remained.

Nine of these publications concerned clinical experimental studies known as the DECREASE studies and follow-up studies of the patients included in them.

- Four of these publications related to the DECREASE-1 study; these are discussed in Section 2.3. Two of these publications are also discussed in Section 2.1, with regard to the "findings from forensic statistical methods".
- Five of these publications related to the DECREASE-2 to DECREASE-5 studies, which have already been studied by the two previous committees. For the sake of completeness, those committees' conclusions on these five studies are summarized in Appendix 2.

One publication related to an experimental study for which the Erasmus MC was not the responsible institution under the WMO (Medical Research involving Human Subjects Act) definition. The authors in this case had participated in a study in which the responsible institution was a pharmaceutical company, which was responsible for the quality control of the data collected. The Committee has no indication that the responsibility for the quality control of this

study was insufficiently managed, and therefore refrained from further investigations regarding this publication.

Two publications that are not directly related to the DECREASE studies have already been examined by the Follow-up Investigation Committee of 2012 [2]. The Committee's conclusions on these two studies have also been summarized in Appendix 2. With regard to the findings from forensic statistical methods, the same studies are also discussed in Section 2.1 below.

The other 235 publications reported on observational clinical research. Many articles related one or more items of baseline data to the clinical outcome after a period of follow-up. In most cases, the data concerned patients who had had vascular surgery at the Erasmus MC.

Two Committee members (Professors Peters and Rosendaal) first studied all 235 abstracts and, where necessary, the full text of these publications, to determine whether there was reason to suspect a breach of academic integrity. If both Committee members felt there was reason for suspicion, the publication was studied in more detail. The Committee also decided that even if the two Committee members decided that one of these publications did not give for suspicion, it should nonetheless be studied if it was referred to in European or American medical guidelines (for an overview of these guidelines, see Appendix 3), or if it had been cited at least 50 times. Finally, the Committee decided that closer examination should be given to at least one article by each first author of the 235 publications. This approach yielded 81 publications for further study. It was also decided that this examination would be expanded if the findings regarding these 81 publications generated additional concern. For three aspects, this was the case. Therefore, for these three aspects, all 235 articles were studied in more detail; this is discussed in Section 2.4.

On the basis of this approach, the publications of which Dr Poldermans was the author or coauthor were categorized as shown in the table below. In Appendix 4 (page 27), Table 1 provides a comprehensive overview of these publications, together with the relevant number and category. The right-hand column of the table below indicates the page in this report where publications in the relevant categories can be found.

		Page
Publications not prepared by Dr Poldermans as first author and not conducted under	248	28
his immediate direction, review articles, publications on the design of planned		
research, commentaries, and related publications. These publications are not		
covered in this report.		
Publications of the DECREASE-2 to 5 studies evaluated by previous committees	5	44
Publications from DECREASE-1	4	45
Publications not directly relating to DECREASE studies already evaluated by	2	45
previous committees		
Publication of an industry study	1	45
Publications of observational studies	235	46
Total	495	

Publications by Dr Poldermans registered in PubMed on April 1, 2013

1.3. Research methods

The Committee conducted its investigation as follows:

- To investigate whether forensic statistical methods developed for detecting academic fraud in published data could be applied to Dr Poldermans' oeuvre, the Committee requested the help of an expert in the field, Professor Dr C.A.J. Klaassen of the University of Amsterdam. Professor Klaassen agreed to study the work of Dr Poldermans as an advisor to the Committee.
- 2. The Committee asked the statistician who was a co-author in four publications of the DECREASE-1 study to respond in writing regarding the availability of the study data, and to present the available data to the Committee. The first authors of the 81 publications on observational studies that had been selected for further consideration were sent a questionnaire which, among other questions, asked whether they still had access to the analysis files or databases used for the publication. In this report, "analysis files" refers to the data files used for a specific publication, while "databases" are larger data sets used as a basis for one or more analysis file. The authors were asked to provide the Committee with these files, where available.
- 3. When multiple publications were based on a common database, the decision was made to examine at least one analysis file. For other publications, at least one of the analysis files provided by each first author was investigated. This research was intended to answer two questions:
 - a. Is the published patient information in broad accordance with the data in the analysis files?
 - b. Is the data in the analysis files in broad accordance with the raw data or data in the electronic patient file?

This investigation was performed for the Committee by two external research bureaus: Pallas Health Research and Consultancy (Pallas) and the Tridata Institute for Applied Statistics and Data Analysis (Tridata), the latter being commissioned by the Cardiology Department at Erasmus MC to evaluate the integrity of the DSE (Dobutamine Stress Echo) database. In close consultation with the Head of this Department, the Committee has been allowed to use the results of this evaluation.

- 4. Full texts of publications were analysed closely.
- 5. To verify various facts and to obtain further explanations, the Committee had direct discussions or correspondence with thirteen people (authors, database controllers, heads of departments, a secretary at the Medical and Ethical Review Committee, and members of the Adverse-Event Committee, Safety Committee, and Steering Committee referred to in publication 453).

2. Findings

2.1. Forensic statistical methods

After an initial exploratory study of Dr Poldermans' published work and two previous reports regarding breaches of academic integrity [1,2], Professor Klaassen concluded that the options for applying forensic statistical methods to this work were probably limited. This was due to differences between the breaches of academic integrity in Dr Poldermans' work and those in work by others that Professor Klaassen had previously studied, in which the data was entirely fictitious. Dr Poldermans' publications related to projects that had really been executed, but in some of which the data had been found to be unreliable or partly fictitious. Forensic statistical methods are less suitable for discovering such more limited flaws.

To judge the extent to which forensic statistical methods could nevertheless be useful for the Committee's investigations, Professor Klaassen applied these methods to four publications:

453

Poldermans D, Boersma E, Bax JJ, et al. The Effect of Bisoprolol on Perioperative Mortality and Myocardial Infarction in High-Risk Patients Undergoing Vascular Surgery. N Engl J Med 1999; 341: 1789–1794.

436

Poldermans D, Boersma E, Bax JJ, et al. Bisoprolol reduces cardiac death and myocardial infarction in high-risk patients as long as 2 years after successful major vascular surgery. Eur Heart J 2001; 22: 1353–1358.

264

Feringa HHH, Elhendy A, Bax JJ et al. Baseline plasma N-terminal pro-B-type natriuretic peptide is associated with the extent of stress-induced myocardial ischemia during dobutamine stress echocardiography. Coron Art Dis 2006; 17: 255–259.

260

Feringa HHH, Bax JJ, Elhendy A, et al. Association of plasma N-terminal pro-B-type natriuretric peptide with postoperative cardiac events in patients undergoing surgery for abdominal aortic aneurysm or leg bypass. Am J Cardiol 2006; 98: 111–115.

The first two publications, which relate to randomized clinical trials, were chosen because the study in question – DECREASE-1 – has had a considerable impact on medical guidelines. Neither publication was studied by the two previous committees.

The second two publications, which relate to observational clinical follow-up studies, were chosen because the investigations of the Follow-up Investigation Committee of 2012 showed that they had been based on data that was largely incorrect. The assumption adopted by Professor Klaassen and the Committee was that if breaches of academic integrity could not be demonstrated by applying forensic statistical methods to the third and fourth publications, these methods could not be applied to the tasks facing the Committee.

Forensic statistical analyses did not identify internal inconsistencies in the statistical results in any of the four publications. Since the two most recent studies were based on data that was largely incorrect, Professor Klaassen concluded that the forensic statistical methods he had previously applied to other work could not be used to investigate Dr Poldermans' work. As a result, these methods were not applied to other publications.

2.2. The availability of data

The statistician who was a co-author in four publications on the DECREASE-1 study was able to provide the Committee with the analysis file for one of these publications (440). According to his report, the files on the remaining publications were no longer available.

Of the 81 questionnaires regarding observational clinical studies that the Committee sent out, 72 were completed and returned. From 31 of the 35 first authors it had approached, the Committee received at least one completed questionnaire.

With regard to observational clinical studies, the questionnaires completed by the first authors enabled the Committee to recover the analysis files for 33 of the 81 publications involved. The analysis file of 11 of these publications were supplied to the Committee by the first authors themselves. The analysis files for the remaining 22 publications were available from one of the co-authors.

The responses in the questionnaires led the Committee to conclude that the researchers had not used CRFs or other written forms to collect data for observational clinical studies. Instead, data had been taken directly from patient files or other primary sources and entered in databases or analysis files.

2.3. Findings with regard to publications relating to the DECREASE-1 study

The Committee focused on the following publications in relation to the DECREASE-1 study:

377.

Kertai MD, Boersma E, Bax JJ, Thomson IR, Cramer MJ, van de Ven LL, Scheffer MG, Trocino G, Vigna C, Baars HF, van Urk H, Roelandt JR, Poldermans D; Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography (DECREASE) Study Group. Optimizing long-term cardiac management after major vascular surgery: Role of beta-blocker therapy, clinical characteristics, and dobutamine stress echocardiography to optimize long-term cardiac management after surgery. Arch Intern Med. 2003; 163:2230-5.

436.

Poldermans D, Boersma E, Bax JJ, Thomson IR, Paelinck B, van de Ven LL, Scheffer MG, Trocino G, Vigna C, Baars HF, van Urk H, Roelandt JR; Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography Study Group. Bisoprolol reduces cardiac death and myocardial infarction in high-risk patients as long as 2 years after successful major vascular surgery. Eur Heart J 2001; 22: 1353-1358.

440.

Boersma E, Poldermans D, Bax JJ, Steyerberg EW, Thomson IR, Banga JD, van De Ven LL, van Urk H, Roelandt JR; DECREASE Study Group (Dutch Echocardiographic Cardiac Risk Evaluation Applying Stress Echocardiography) Predictors of cardiac events after major vascular surgery: Role of clinical characteristics, dobutamine echocardiography, and beta-blocker therapy. JAMA 2001; 285: 1865-1873.

453.

Poldermans D, Boersma E, Bax JJ, Thomson IR, van de Ven LL, Blankensteijn JD, Baars HF, Yo TI, Trocino G, Vigna C, Roelandt JR, van Urk H. The effect of bisoprolol on perioperative mortality and myocardial infarction in high-risk patients undergoing vascular surgery. N Engl J Med 1999; 341: 1789-1794.

2.3.1. Analysis files

The only analysis file the Committee was able to access was the file for publication 440. If a few discrepancies are disregarded, the patient information referred to in this publication generally accorded with the data in the analysis file.

As publication 453 relates to patients who were also subjects in publication 440, it was possible to compare some of the patient information reported in publication 453 with the analysis file of publication 440. This information again proved to be broadly congruent. Neither the remaining patient information for publication 453, nor the entirety of the patient information for publications 377 and 436, were included in the analysis file for publication 440.

Since the analysis file did not include patient identification numbers, it was not possible to verify whether the patient data found in the patient files matched with the inclusion criteria and the outcomes shown in the analysis file and the publication.

The comparisons of data described above were carried out by Pallas.

2.3.2. Interviews with those involved

As the DECREASE-1 study was an open-label study (with bisoprolol), the Committee focused particularly on whether proper procedures had been used to establish its outcomes. The Committee also examined the way in which the early termination of the study had come about.

The Committee proceeded on the basis of the research protocol for the study (which was later known as the DECREASE-1 study) that was available in the archive of the METC. While the researchers stated that a there was a newer version of this protocol, the Committee did not find such a document in the documentation available at the METC.

Determination of outcomes:

The protocol available states the following: "All study outcomes will be evaluated by an External Auditing Committee comprising three experienced, independent clinicians."

The relevant publication in the *New England Journal of Medicine* (no. 453) makes no mention of an External Auditing Committee, but rather of an "adverse event committee" consisting of two cardiologists from the Department of Cardiology at Erasmus MC. The methods section of this publication states that: "All data were collected by the participating centers and evaluated in a masked fashion by members of the adverse events committee." The Committee observes that (apart from details such as the naming and the number of experts) the methods section essentially agrees with the protocol used by the Committee.

The Committee's interviews with the two members of the adverse event committee mentioned in the article revealed that one could only remember that he had evaluated ECGs which the researcher (Dr Poldermans) had presented to him. The other member could not recall anything about his possible participation in this project. Neither was aware that they had been named in the article as members of this Committee.

However, the first author (Dr Poldermans) and the last author testified that data on all DECREASE-1 patients thought to have a relevant study outcome were presented to the two cardiologists (the members of the adverse event committee), and that they had access to all the necessary data.

Interim analysis

The protocol used by the Committee also states: "*After six months, the safety and efficacy committee will make an interim evaluation of the study results.*"

In publication 435, a "safety committee" is mentioned. The methods section of publication 453 states: "As part of the study design, an interim analysis by an independent safety committee was planned after enrolment of the first 100 patients". In this respect (apart from the timing of the interim analysis) the methods section essentially agrees with the protocol used by the Committee as well.

The results section of this paper reports:

"The significant difference between groups in the incidence of serious cardiac events prompted the safety committee to interrupt the study after the planned interim analysis. While the safety committee was evaluating the results, six additional patients underwent randomization."

The Committee's interviews with the two members of the "safety committee" mentioned in the article revealed that neither remembered participating in a "safety committee" or contributing to the analysis of the relevant data. One of these members did remember providing advice by telephone about "stopping rules" in general. The other member recalled a telephone conversation about extreme findings with the principal investigator, in which he had been asked for advice. Neither was aware that this article named them as members of this committee.

The first author (Dr Poldermans), the statistician who was a co-author, and the last author confirmed that, despite the statement made in the publication, the decision to stop the study was not taken by the safety committee, but by the executive board of the so-called steering committee, which consisted of three of the authors including Dr Poldermans. The first author (Dr Poldermans), the statistician/co-author, and the last author reported that the members of the

safety committee were thoroughly informed about the findings and were consulted, and that their recommendations were decisive.

2.4. Findings with regard to observational clinical research

2.4.1. Analysis files

DSE database

The analysis files of 14 publications whose analysis files were available had been derived from the DSE database managed by the Department of Cardiology. As explained in 2.2. above, these publications were among the 81 publications closely examined. A few dozen studies of the remaining 154 publications were also based on the DSE database. This database was studied by the Tridata Institute, together with two articles selected from the 14 publications based on the database. Tridata reports the following regarding the DSE database:

"On the basis of the audit of the DSE database, we have reached the following conclusions:

- 99.59 % of all patients in the DSE database could be traced through their ZIS numbers (personal ID number) in the Erasmus MC patient file system.
- 94.47% of all patient appointments in the DSE database could be found in exactly the same form in the Erasmus MC patient file system. If we allow a one-day difference between the dates in these two data systems, this increases to 96.39 %.
- By linking the local government population register (GBA) to the DSE database, it is possible to determine the complete set of possible follow-up candidates."

In broad terms, the results published in the two articles selected could be reproduced from the analysis files. Although there are differences in the analytical results, these might be attributable to the use of different statistical programmes.

With regard to the analysis files for the two selected publications, the Committee observes that, per patient, there are three logical possibilities relating to study outcomes, such as cardiovascular complications or specific causes of death found at follow-up. Either:

- 1. the researcher knows that the outcome did occur in this patient, or
- 2. the researcher knows that the outcome did not occur in this patient, or
- 3. the researcher knows nothing about this outcome for this patient (a missing value).

The manager of the DSE database has shown the Committee that the database does record, for each patient, whether he or she matched possibility 1, 2, or 3. However, in the analysis file for the publication, the authors had chosen to reduce this to two possibilities: 1 (1) or 0 (2 or 3). In these publications, it is therefore impossible to distinguish between situations in which the outcome did not occur and those in which the researcher did not know whether it occurred. This could have distorted the results.

ECHO database

The Committee also gathered information on the ECHO database, which also included data that was used for the purposes of compiling analysis files for research studies. This database is managed by the Department of Anaesthesiology, but because it was revised in 2012, it is no

longer possible to reliably trace the data underlying older analysis files. This meant that the analysis files for at least five of the 81 publications selected for closer study could not be scrutinized.

Remaining files

In addition to those of the 14 publications based on the DSE database, the analysis files of 19 additional publications were available. On the basis of the selection rules defined in see Section 1.3, seven of these were examined.

The general picture that emerged was as follows:

- Except for a few discrepancies and careless errors, the patient information published in the articles generally agreed with the data in the analysis files.
- Three analysis files made it possible to verify the original patient information in the electronic patient file. This allowed all patients in a number of random samples to be traced. One of the analysis files also enabled the Committee to verify the inclusion criteria in the patient files, where only minor discrepancies were encountered.
- In some of the analysis files that were studied, as in the two analysis files derived from the DSE database that were discussed above, no distinction was made between missing values and the non-occurrence of the outcome with regard to cause of death and cardiovascular events.

2.4.2. Textual analysis

Many of the 81 studies selected for closer examination linked preoperative clinical data to a long-term clinical outcome. Examples of preoperative clinical data included the patient's gender, kidney function, QRS width in the ECG, and plasma phosphate levels. Many of these publications did not report that, in many cases, major surgery had occurred between the baseline assessment and the long-term outcome.

On the basis of its textual analyses of these 81 publications, the Committee made a number of findings which can be divided into three categories:

- 1. Reports that the METC had approved the study.
- 2. Reports that informed consent had been requested and obtained.
- 3. Reports on the completeness of follow-up data.

Since such reports were quite frequent within the 81 selected publications, the Committee decided to search the other 154 articles specifically for such statements. The results of this two-stage analysis are shown below for all 235 articles.

1. Reports that the METC had approved the study

The protocols of studies that fall under the Medical Research involving Human Subjects Act (WMO) must be reviewed and approved by the Medical and Ethical Review Committee (METC) before the study begins. Research is subject to the WMO if it satisfies two conditions:

- It is scientific medical research involving human subjects, and
- People receive treatment or are asked to follow specific rules of conduct.

Whereas experimental research in the Netherlands is always subject to the WMO, observational research is not, providing the treatment or rules of conduct whose effect is being observed are part of the health care routine. The Committee considers that, according to these basic principles, a large majority of the studies described in these publications were not subject to the WMO. In four cases that the Committee considered doubtful, the relevant publication was presented to a METC secretary who was responsible for preparing for decisions on whether research proposals are subject to the WMO. She concluded that, solely on the basis of reading the publications (and thus without reference to the original research protocol), no reliable and definitive answer could be given on whether these studies fell under the WMO.

In the 235 publications, the Committee found the following statements:

- *The METC approved the study* (51 times).
- *The METC approved the protocol* (91 times: in one case the protocol was found in the METC archives).
- Patients were included after approval by the Medical Ethics Committee (6 times).
- Patients were included and the local government population register was approached after prior approval by the METC (1 time).
- The METC was informed about the research protocol but, in line with the agreed policy, was not asked for official approval (9 times)
- The participating hospitals satisfied requirements laid down by the local METC (3 times).
- *The METC approved the DSE protocol* (11 times)
- The METC was informed, and agreed to the procedures (1 time)

The other 62 publications did not mention METC approval.

To the extent that the Committee has been able to establish this on the basis of the METC archive, only one protocol of the 235 studies described in these publications was submitted to the METC for official examination and approval. As stated above, it is the Committee's opinion that, with the possible exception of four studies, such approval was not necessary.

Correspondence with the researchers showed that a statement that the METC had given its approval should be understood to mean that the METC: 1) was aware that researchers were conducting research that did not fall under the WMO, and 2) agreed that protocols for such studies would not be submitted for its examination and approval. The researchers also stated that, in case of doubt, the question was discussed with the METC chairperson. On this, however, the METC archives provided no information.

2. Reports that informed consent had been requested and obtained

"Informed consent" for participation in scientific research means that, after having been informed about the specific research project in detail, both verbally and in writing, patients or the subjects in a trial are asked to agree to participate in that project by signing a form. The emphasis in the definition of informed consent lies on the requirement that patients should be informed specifically about the study in question. This makes informed consent essentially different from asking patients whether they object to the use of their data for scientific research in general.

Written informed consent is legally required for research falling under the WMO. In recent years it is also becoming usual for research that is *not* required to comply with the WMO, especially

under two conditions: 1) if it is clear in advance that the patient data and results of clinical or other examinations will be used for a study, and 2) it is possible to ask for consent. For most of the studies in question, however, it is the Committee's opinion that informed consent was not required.

In publications on observational clinical research, the authors made the following statements about informed consent:

- Reports of informed consent (134 times)
- Reports of written informed consent (2 times)
- *The patients agreed to participate* (6 times).
- Because of the retrospective character of the study, it was not possible to ask each patient for *permission* (1 time)
- Patients gave permission for the use of their data (4 times)

In 88 publications, nothing was said about informed consent, or it was stated that informed consent was not necessary.

Correspondence with the researchers shows that it was usual for the principal investigator to ask all patients who visited the outpatient clinic to agree verbally to the use of their data for research purposes. The questions and answers were not systematically recorded.

3. Reporting on the completeness of follow-up data

As outcome measures, most of the studies discussed here used mortality or a combination of mortality (in some cases specified by cause of death) and non-fatal myocardial infarction. With regard to these outcomes, some of these publications gave incomplete information on the extent to which follow-up was complete. It was often reported that the follow-up was 100% or close to 100%. Correspondence with the researchers showed that in such cases their intention was to indicate that this high follow-up rate had been attained for the outcome of total mortality (without cause of death). While in most cases, this data could be derived from the local government population register, the same was not true of the cause-specific mortality or other outcomes mentioned in the publication, for which it was considerably more difficult to obtain information. Some researchers pointed out that the relevant publication made no explicit claim about the completeness of the other follow-up data. However, many of the publications examined here do not inform the reader about specific follow-up rates for cause-specific mortality of the results.

With regard to important follow-up outcomes (cause of death or cardiovascular diseases), the Committee found the following information in the publications:

- 1. Unclear or incomplete follow-up reporting (101 times):
 - with a follow-up rate calculated for the total study population, which implies that the follow-up rate was 100% for all study outcomes (72 times)
 - with a follow-up rate calculated for the number of patients with the status "dead" or "alive" for whom follow-up was complete (15 times)
 - with no percentages stated for cause of death or myocardial infarct, just absolute numbers without reporting missing values (9 times)
 - other (5 times)

- 2. Complete or clear follow-up reporting (19 times):
 - the cause of death was based on CBS data, making it complete for all cases in which subjects had died (1 time)
 - mortality was assumed to be cardiac, unless there were explicit indications to suppose that it was not (4 times)
 - complete reporting: the percentage of patients for whom the outcome was unknown, or could be derived from the table or text (12 times)
 - full follow-up was implicitly or explicitly claimed, and, in view of the small number of patients, was indeed possible (2 times).

In 115 cases, specific long-term follow-up was not applicable.

Appendix 4, Table 2 provides an overview of the findings regarding METC approval, informed consent, and follow-up data for each publication.

3. Conclusions

3.1. Definition of academic misconduct

In accordance with its terms of reference, the Committee investigated indications for breaches of academic integrity in publications by Dr Poldermans. As its definition of a breach of academic integrity, the Committee has used the description of academic misconduct in the Erasmus MC Research Code of March 2011, Chapter 2.2, which states:

"The concept of academic misconduct extends at least to the following:

- a. falsifying data;
- b. secretly omitting unfavourable results;
- c. entering fictitious data;
- d. deliberately misusing statistical methods to achieve conclusions other than those justified by the data;
- e. deliberately interpreting results and conclusions falsely;
- f. plagiarizing results or other authors' publications;
- g. pretending to be an author or co-author, or deliberately omitting to mention other authors;
- h. failure to exercise due care when conducting research;
- i. the theft of intellectual property."

3.2. Conclusions on the availability of data

In view of the period in which the data in question was collected – the 1990s – it is the Committee's opinion with regard to the DECREASE-1 study (see Section 2.3) that the lack of raw data, analysis files, and the absence of a file with patient identification numbers cannot be described as breaches of academic integrity.

Because of how long ago the research was executed, the inability to locate the version of the METC protocol, that according to the investigators was used during the study, is in the opinion of the Committee not an indication for a breach of academic integrity. Moreover, the version of the protocol that was available essentially agreed with the methods section of the relevant publication.

Today, it would generally not be regarded as conducive to proper control of research procedures if data for observational clinical studies were collected without using CRFs or other written forms, and if data from medical dossiers and other primary sources were entered directly into statistical analysis files. Nevertheless, the currently recommended procedures are still often not applied by researchers conducting studies which do not fall under WMO regulations. Therefore, also given the years during which most of the studies under discussion were performed, the Committee holds that the procedures followed in these studies cannot be considered breaches of academic integrity.

The Committee attempted to trace the analysis files relating to the 81 publications on observational clinical studies. These efforts were successful in 33 cases. As the Dutch legislation and regulations on the preservation of this data are ambiguous [3,4,5,6], the Committee considers that the limited availability of this data cannot be construed as a breach of academic integrity.

3.3. Conclusions about the DECREASE-1 study

With regard to the conduct of the DECREASE-1 study, the written documentation of the research process is largely lacking. Various explanations could be given for the discrepancies that have been noted between publications 440 and 453, and the analysis file for publication 440. After the passage of 15 years, these explanations cannot be tested.

There were wide differences in the memories of those involved regarding the way in which outcomes had been determined in the DECREASE-1 study. Similar to the first author of publication 453 (Dr Poldermans), the last author claimed that these determinations were made in accordance with the stipulations defined in the protocol and reported in the publication. The members of the adverse event committee cannot confirm this.

Regarding the decision to prematurely terminate the DECREASE-1 study, the Committee finds that this decision was not taken by the safety committee, as suggested in publication 453, but by the three members of the executive board of the steering committee. Apart from this inaccuracy, memories of how closely the members of the safety committee were involved in the decision-making differ between those concerned.

On the basis of these findings, the Committee is unable to confirm or dispel doubts about neither the care with which the DECREASE-1 study was conducted – and thus about the study's integrity – nor about the reliability of its results.

3.4. Conclusions with regard to observational clinical research

3.4.1. Analysis files

The analysis files were available for 33 of the 81 publications examined. Nine were examined more closely: two belonging to the 14 publications that were based on the DSE databases, and seven to the 19 remaining publications,

The DSE database – which also underlies several dozen of the remaining 154 articles that were not examined – was found to be very reliable. The two analysis files that were selected from the DSE showed good general agreement with the relevant articles. Similarly, apart from some minor discrepancies and careless errors, seven of the 19 remaining files that were available showed general agreement with the relevant articles. Five of the nine analysis files that were examined showed that it was possible to compare original patient information with the research data. This revealed general agreement with the research data. Based on these findings, the Committee did not find indications for breaches of academic integrity.

As the nine analysis files examined were essentially representative of the remaining 24 analysis files available – for example they either concerned the same patients, were derived from the same database, or both – the Committee decided not to examine all 24 files. On the basis of the same finding, the Committee also believed that it would be unnecessary to extend its activities by attempting to trace the analysis files for the remaining 154 observational studies. The Committee arrived at this conclusion also by considering the magnitude of the necessary investment in

labour and public means that would be required for substantially expanding the scope of the investigation, weighed against the expectation of a limited additional yield. Although the Committee cannot pass any judgement on the analysis files it did not investigate, following its terms of reference the Committee searched for indications of academic integrity breaches in a relevant selection of available material, and did not find them.

However, it is remarkable that a number of the analysis files did not distinguish between the nonoccurrence of an outcome and the researcher's lack of knowledge about whether it had occurred. It is evident that this could bias the study conclusions. This is also relevant in failures to report incomplete follow-up for important outcomes, which are discussed below in Section 3.4.2.

3.4.2. Textual analysis

As reported in paragraph 2.4.2, the Committee believes that a number of published statements indicate that academic integrity was breached. This opinion is based on the criterion for academic misconduct formulated in Chapter 2.2 paragraph (h) of the Erasmus MC Research Codes, "failure to exercise due care when conducting research".

This concerns the following statements:

In relation to approval by the METC

- The METC approved the study
- The METC approved the protocol
- Patients were included after approval by the METC, and
- Patients were included and the local government population register was approached after prior approval by the METC

In relation to follow-up data

- Unclear or incomplete reporting of the extent to which follow-up data was complete.

In the Committee's opinion, various consequences flow from a number of these shortcomings:

While the Committee considers it to be unacceptable that approval by the METC was reported incorrectly in relation to studies that did not need to be approved by the METC and where no approval was given, this did not influence the results of the research or the interpretation of those results. In the four cases in which examination and approval by the METC may have been necessary, the consequences of incorrect reporting on this point would have been much more serious. But since in these cases it cannot be established on the basis of those publications alone whether these observational studies did fall under the WMO requirements, the Committee cannot reach any clear conclusions on this point.

In the Committee's opinion, the failure to report incomplete follow-up for important outcomes has much greater implications for the study findings than the incorrect reports of informed consent and approval by the METC. The Committee considered whether in this case there was not only "failure to exercise due care when conducting research", but also a breach of academic integrity as defined in Chapter 2.2 paragraph (d) of the Erasmus MC Research Code: "deliberately misusing statistical methods to achieve conclusions other than those justified by the data." However, the Committee's view is that it is not certain that the authors who gave

incomplete information about the follow-up did so deliberately in order to support conclusions that differed from those justified by the data. The Committee is thus of the opinion that while there are no indications of breaches of academic integrity on the basis of Chapter 2.2 paragraph (d) of the Erasmus MC Research Code, there are indeed such indications on the basis of Chapter 2.2 paragraph (h).

It is nonetheless clear that the degree of completeness of the follow-up data was not adequately reported in a substantial number of publications, except for total mortality in the patients who were followed up; and that it is unlikely that the follow-up was in fact complete for the non-fatal outcomes, especially regarding myocardial infarctions. In certain cases this may have distorted the results, and erroneously added greater weight to the findings than justified by the data.

With regard to the many reports of informed consent referred to in paragraph 2.4.2, the Committee observes on the basis of the researchers' statements that where a publication reports informed consent, this probably refers to oral permission for the use of patient data, and not to informed consent in the actual sense of the term. The Committee is also of the opinion that, in many cases, it was not necessary to ask for informed consent. Such an approach is not consistent with acceptable standards for the transparent reporting of scientific procedures. However, in view of: 1) the period in which much of this research was done, and 2) the evolving notions with regard to the correct interpretation of the concept of "informed consent" for research that does not fall under the WMO requirements, the Committee does not view the qualification "breach of academic integrity due to failure to exercise due care when conducting research" to be applicable to these reports.

4. Recommendations

4.1. Recommendations with regard to the DECREASE-1 study

Because only limited written and digital data on the DECREASE-1 study is available, and as participants' memories differ with regard to how outcomes were determined and how the decision to end the study was taken, further investigation of possible breaches of academic integrity in this study is not advisable.

The DECREASE-1 study contributed to the formulation of European and American clinical guidelines, whose next revision is now being discussed. The Committee recommends that the present report should be brought to the attention of the organizations responsible for revising the relevant guidelines.

The Committee also recommends that this report should be sent to the editorial boards of the journals that published the relevant articles.

4.2. Recommendations with regard to the observational clinical research

4.2.1. Analysis files

In the files it examined, the Committee found no indications that academic integrity had been breached in relation to the inclusion of patients and the results of the analyses. There are nonetheless concerns about the discrepancies and careless errors found in a number of publications. The Committee recommends measures aimed at prevention and control, based on meticulous documentation of research procedures as well as research data.

4.2.2. Textual analysis

Regarding the involvement of the METC, the reporting of informed consent, and the completeness of the follow-up data, the defects in a number of publications appear to be related to flaws in the research culture during the period in which the research was being conducted. Since such flaws are not necessarily unique for this case, the Committee recommends measures aimed at reinforcing and promoting a more conscientious research culture. Supervision and constructive critique by one's colleagues play an essential role in preventing incorrect practices.

The Committee recommends that the editorial boards of the journals that published the articles considered here should also be sent this report. On the basis of the information it contains, the editors can make their own decisions with regard to acting on the Committee's findings. While incorrect reporting on informed consent and approval by the METC cannot be justified, it had no effect on the research results. As for the possible incompleteness of follow-up information, it is impossible to determine to what extent this was also ignored in the analyses and to what extent it affected the results. By affecting the weight that readers gave to the findings, incomplete information may also have created an incorrect picture in their minds.

4.3. Patients

This report makes no recommendations with regard to action involving patients. The DECREASE-1 study was of clear importance to patients, and received considerable attention in

the professional and general media. The Committee's report has produced no new insights in this respect. Considering that the patients who were included in the 235 observational studies experienced no changes to the clinical care they were provided, they were not exposed to any additional risk as a consequence of the research study. The Committee verified whether these publications influenced the phrasing of medical guidelines in such way that patients may have been harmed. The Committee is convinced that this did not occur.

4.4. Data storage

As the Committee has explained, due to the ambiguity of Dutch legislation and regulations on the preservation of data, the unavailability of research data for many of the studies in question cannot be characterized as a breach of academic integrity. Nevertheless, the Committee sees a lack of good record keeping and storage for research data as an impediment to good quality control in scientific activities. A solution to this problem will depend on the development by the scientific community of a clear and consistent policy on data storage.

Appendix 1

Terms of reference

February 5, 2013

The Dean and Board of Erasmus MC has decided to establish the "Follow-up Investigative Committee (Academic Integrity) of 2013," referred to below as the Committee.

The Committee has been established to act on the general recommendation of the Follow-up Investigation Committee of 2012 that further investigation of Dr D. Poldermans' publications would be indicated if compelling new scientific or societal arguments were to arise in relation to specific components of his oeuvre (see the Report of The Follow-up Investigation Committee of 2012, September 2012).

The Committee is to study all publications in which Dr Poldermans is listed as an author or coauthor and to select those that report on research conducted by Dr Poldermans himself or under his immediate direction.

The Committee is to investigate, to the extent possible, whether there are indications of breaches of academic integrity in the preparation of these publications. Priority is to be given to frequently cited publications and those that have contributed significantly to the formulation of medical guidelines.

Where possible, the Committee is to use statistical methods developed for detecting scientific fraud in published data.

The provisional Committee membership is:

- Dr P.J. van der Maas, Emeritus Professor of Social Health Care, Erasmus MC, Chairperson
- Dr R.J.G. Peters, Professor of Cardiology, AMC
- Dr F.R. Rosendaal, Professor of Clinical Epidemiology, LUMC
- Dr J.M.W. Hazes, Professor of Rheumatology, Erasmus MC

Administrative support will be provided by Dr R.E. Juttmann of the Department of Research Policy. For technical aspects of its investigations, the Committee may request assistance from external experts.

The Committee is requested to inform the Board about its progress every two months, and to indicate before 1 July 2013 when it expects to complete its work.

Appendix 2

Summary of the findings of the previous committees

DECREASE-2 and the follow-up study known as DECREASE-5 (publications 121, 214 and 243)

The Committee considered the conduct of these studies to be negligent and/or scientifically incorrect with regard to the following:

- Negligence in following the informed consent procedure.
- Incomplete source documentation for a project subject to the WMO and conducted less than 15 years ago.
- The considerable number of discrepancies revealed by comparisons of the source documents, electronic patient files, and the study database. There were particularly significant discrepancies between source documents (especially regarding written patient data from other hospitals, General Practitioners, etc.), and the conclusions drawn from them as to the patients' risk profiles (a core element of the study).
- Serious deviations from the research protocol approved by the METC regarding the evaluation of Dobutamine Stress Echos (DSEs).
- The way the clinical outcomes were determined for this study, which deviated in practice from the protocol and the published report. Although the protocol provided for independent evaluation of the outcomes by a group including two cardiologists, and although the publication spoke of an adverse event committee, no such independent evaluation took place.

In the opinion of the Committee, the available information makes it impossible to vouch either for the reliability of the findings in the publications, or for the validity of their conclusions.

DECREASE-3 (publication 98)

Leaving aside the fact that the informed consent forms are no longer available for a project subject to the WMO and conducted less than 15 years ago, the Committee found no indications of breaches of academic integrity in the evaluation of this project. On the basis of multiple statements from witnesses, the Committee concludes that written informed consent was obtained in accordance with the procedure approved by the METC.

DECREASE-4 (publication 114)

The Committee considers that the conduct of this study was negligent and/or scientifically incorrect in the following respects:

- Incomplete source documentation for a project subject to the WMO and conducted less than 15 years ago.
- An inclusion rule was changed without validation and without permission from the METC.
- The manner by which patient outcomes were verified. While the protocol provided for independent evaluation of possible perioperative cardiovascular complications (the primary outcome of the study) by an adjudication committee consisting of three experts (a cardiologist, a surgeon and an anaesthetist), this was not done. The outcomes were determined by the researcher running the study and by a vascular surgeon.
- Failure to record and report the basis by which each outcome was determined.

In the Committee's opinion, the available information makes it impossible to vouch either for the reliability of the findings in the publication, or for the validity of the conclusions.

Studies published in publications 260 and 264

- The analysis file on which these publications are based is filled largely with data that did not accord with the facts (fictitious data).
- The substance of these publications can be fully reconstructed from this analysis file.
- The Committee considers it improbable that this analysis file was fabricated retrospectively by someone with malicious intent who wished to discredit these publications and who took the existing publications as a starting point. The Committee is therefore convinced that the analysis file was created as part of the scientific process in question, where its analysis would lead to the production of the relevant publications.
- As the first author and the principal investigator have given contradictory accounts of how the data was produced, the Committee cannot conclude who may be responsible for creating this fictitious data. Each person blames the other, and both state that they never checked the research data against the patient information.
- Due to the discrepancies between the authors' explanations and the text of the publications, the Committee considers the reporting of this study to have been negligent and scientifically incorrect.

Medical guidelines

European Society of Cardiology

- Peripheral Artery Diseases (Diagnosis and Treatment of)
- Guidelines on myocardial revascularization
- Guidelines for pre-operative cardiac risk assessment and perioperative cardiac management in non-cardiac surgery

American College of Cardiology/American Heart Association

- Guidelines for the Management of Patients With Peripheral Arterial Disease (Lower Extremity, Renal, Mesenteric, and Abdominal Aortic)
- 2009 ACCF/AHA focused update on perioperative beta blockade incorporated into the ACC/AHA 2007 guidelines on perioperative cardiovascular evaluation and care for noncardiac surgery.

Trans-Atlantic Inter-Society Consensus Document on Management of Peripheral Arterial Disease (TASC II)

Table 1

Overview of publications by Dr D. Poldermans

Table 1 provides a comprehensive overview of these publications, together with the relevant number and category. The right-hand column of the table below indicates the page in this report where publications in the relevant categories can be found.

		Page
Publications not prepared by Dr Poldermans as first author and not conducted under	248	28
his immediate direction, review articles, publications on the design of planned		
research, commentaries, and related publications. These publications are not		
covered in this report.		
Publications of the DECREASE-2 to 5 studies evaluated by previous committees	5	44
Publications from DECREASE-1	4	45
Publications not directly relating to DECREASE studies already evaluated by	2	45
previous committees		
Publication of an industry study	1	45
Publications of observational studies	235	46
Total	495	

Publications not prepared by Dr Poldermans as first author and not conducted under his immediate direction, review articles, publications on the design of planned research, commentaries, and related publications. These publications are not covered in this report:

2. Catapano AL, Reiner Z, De Backer G, Graham I, Taskinen MR, Wiklund O, et al. ESC/EAS Guidelines for the management of dyslipidaemias The Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS). Atherosclerosis. 2011 Jul;217(1):3-46.

3. Vidakovic R, Poldermans D, Neskovic AN. Preoperative cardiac risk management. Acta Chir Iugosl. 2011;58(2):9-18.

5. Hamm CW, Bassand JP, Agewall S, Bax J, Boersma E, Bueno H, et al. ESC Guidelines for the management of acute coronary syndromes in patients presenting without persistent ST-segment elevation: The Task Force for the management of acute coronary syndromes (ACS) in patients presenting without persistent ST-segment elevation of the European Society of Cardiology (ESC). Eur Heart J. 2011 Dec;32(23):2999-3054.

6. Regitz-Zagrosek V, Blomstrom Lundqvist C, Borghi C, Cifkova R, Ferreira R, Foidart JM, et al. ESC Guidelines on the management of cardiovascular diseases during pregnancy: the Task Force on the Management of Cardiovascular Diseases during Pregnancy of the European Society of Cardiology (ESC). Eur Heart J. 2011 Dec;32(24):3147-97.

7. Tendera M, Aboyans V, Bartelink ML, Baumgartner I, Clement D, Collet JP, et al. ESC Guidelines on the diagnosis and treatment of peripheral artery diseases: Document covering atherosclerotic disease of extracranial carotid and vertebral, mesenteric, renal, upper and lower extremity arteries: the Task Force on the Diagnosis and Treatment of Peripheral Artery Diseases of the European Society of Cardiology (ESC). Eur Heart J. 2011 Nov;32(22):2851-906.

10. Hoeks SE, Bouw E, Poldermans D. Quality assurance in perioperative care. Best Pract Res Clin Gastroenterol. 2011 Jun;25(3):435-41.

11. Goncalves FB, Koek M, Verhagen HJ, Niessen WJ, Poldermans D. Body-mass index, abdominal adiposity, and cardiovascular risk. Lancet. 2011 Jul 16;378(9787):227; author reply 8.

12. Catapano AL, Reiner Z, De Backer G, Graham I, Taskinen MR, Wiklund O, et al. ESC/EAS Guidelines for the management of dyslipidaemias: the Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS). Atherosclerosis. 2011 Jul;217 Suppl 1:S1-44.

13. Reiner Z, Catapano AL, De Backer G, Graham I, Taskinen MR, Wiklund O, et al. ESC/EAS Guidelines for the management of dyslipidaemias: the Task Force for the management of dyslipidaemias of the European Society of Cardiology (ESC) and the European Atherosclerosis Society (EAS). Eur Heart J. 2011 Jul;32(14):1769-818.

14. Bakker EJ, Ravensbergen NJ, Poldermans D. Perioperative cardiac evaluation, monitoring, and risk reduction strategies in noncardiac surgery patients. Curr Opin Crit Care. 2011 Oct;17(5):409-15.

15. Bakker EJ, Ravensbergen NJ, Voute MT, Hoeks SE, Chonchol M, Klimek M, et al. A randomised study of perioperative esmolol infusion for haemodynamic stability during major vascular surgery; rationale and design of DECREASE-XIII. Eur J Vasc Endovasc Surg. 2011 Sep;42(3):317-23.

16. Howell SJ, Hoeks SE, Poldermans D, West RM, Wheatcroft SB. OBTAIN: a study of the occurrence of bleeding and thrombosis during anti-platelet therapy in non-cardiac surgery. Eur J Anaesthesiol. 2011

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Jun;28(6):456-9.

17. Voute MT, Hendriks JM, van Laanen JH, Pattynama PM, Muhs BE, Poldermans D, et al. Radial force measurements in carotid stents: influence of stent design and length of the lesion. J Vasc Interv Radiol. 2011 May;22(5):661-6.

19. Ng AC, Delgado V, Bertini M, Antoni ML, van Bommel RJ, van Rijnsoever EP, et al. Alterations in multidirectional myocardial functions in patients with aortic stenosis and preserved ejection fraction: a two-dimensional speckle tracking analysis. Eur Heart J. 2011 Jun;32(12):1542-50.

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25. Cacoub PP, Zeymer U, Limbourg T, Baumgartner I, Poldermans D, Rother J, et al. Effects of adherence to guidelines for the control of major cardiovascular risk factors on outcomes in the REduction of Atherothrombosis for Continued Health (REACH) Registry Europe. Heart. 2011 Apr;97(8):660-7.

26. Levy M, Heels-Ansdell D, Hiralal R, Bhandari M, Guyatt G, Yusuf S, et al. Prognostic value of troponin and creatine kinase muscle and brain isoenzyme measurement after noncardiac surgery: a systematic review and meta-analysis. Anesthesiology. 2011 Apr;114(4):796-806.

27. Ravensbergen NJ, Voute MT, Poldermans D. Safety of perioperative beta-blocker use: how do betablockers compare in terms of side effects? Expert Opin Drug Saf. 2011 Jul;10(4):545-58.

28. van de Laar IM, Oldenburg RA, Pals G, Roos-Hesselink JW, de Graaf BM, Verhagen JM, et al. Mutations in SMAD3 cause a syndromic form of aortic aneurysms and dissections with early-onset osteoarthritis. Nat Genet. 2011 Feb;43(2):121-6.

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32. Flu WJ, van Kuijk JP, Bax JJ, Poldermans D. Perioperative beta-blockers: is it still useful? Indian Heart J. 2010 Mar-Apr;62(2):118-22.

33. van Loon JE, Leebeek FW, Deckers JW, Dippel DW, Poldermans D, Strachan DP, et al. Effect of genetic variations in syntaxin-binding protein-5 and syntaxin-2 on von Willebrand factor concentration and cardiovascular risk. Circ Cardiovasc Genet. 2010 Dec;3(6):507-12.

36. Schinkel AF, Bax JJ, Delgado V, Poldermans D, Rahimtoola SH. Clinical relevance of hibernating myocardium in ischemic left ventricular dysfunction. Am J Med. 2010 Nov;123(11):978-86.

37. Voute MT, Winkel TA, Poldermans D. Optimal medical management around the time of surgery. Heart. 2010 Nov;96(22):1842-8.

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40. Goei D, Poldermans D. Screening value of N-terminal pro-B-type natriuretic peptide as a predictor of perioperative cardiac events after noncardiac surgery. Future Cardiol. 2010 Sep;6(5):603-9.

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- Totaal:

Table 2

Overview of noteworthy statements in publications about observational clinical research

Key

METC:

- 1. The METC approved the study.
- 2. The METC approved the protocol.
- 3. Patients were included with the prior approval of the METC.
- 4. The METC gave its prior approval to the inclusions of patients and for requests for data from the local government register of population.
- 5. The METC was informed about the research protocol but, in line with the agreed policy, was not asked for official approval.
- 6. The participating hospitals satisfied requirements laid down by the local METC.
- 7. The METC approved the DSE protocol.
- 8. The METC was informed and agreed to the procedures
- 9. Nothing was said about approval by the METC.

Informed consent

- 1. Reports informed consent.
- 2. Reports written informed consent.
- 3. The patients agreed to participate.
- 4. Because of the retrospective character of the study, it was not possible to ask each patient for permission.
- 5. Patients gave permission for the use of their data.
- 9. Nothing was said about informed consent or it was stated that informed consent was not necessary.

Degree of completeness of the patient follow-up:

Unclear or incomplete follow-up reporting, and

- 1. The follow-up percentage was calculated for the total study population.
- 2. The percentage was calculated for the number of patients with a complete follow-up for the status "dead" or "alive."
- 3. No percentages were given for cause of death or myocardial infarction, only absolute numbers without reporting of missing values.
- 4. Other.

Complete or clear follow-up reporting, and

- 5. The cause of death was based on CBS data, making it complete for all cases in which subjects had died.
- 6. Mortality was assumed to be cardial, unless there were explicit indications to suppose that it was not.
- 7. Correct reporting: the percentage of patients for whom the outcome was unknown was stated, or could be derived from the table or text
- 8. Full follow-up was implicitly or explicitly claimed, and in view of the small number of patients that was indeed possible.
- 9. There was no long term follow-up

Article Nr	METC	Informed consent	Follow-up
1	1	9	2
4	9	9	9
8	1	9	9
9	9	9	4
18	9	9	7
21	1	5	5
22	1	5	9
24	3	1	1
31	5	9	6
34	1	1	9
35	1	9	1
38	4	9	7
43	1	9	1
47	3	1	1
52	3	1	2
53	6	9	9
54	1	9	1
57	1	1	9
59	1	2	1
61	6	1	9
62	1	1	1
64	9	9	9
66	1	2	1
70	1	9	9
73	1	1	9
76	1	1	9
79	3	1	7
80	3	9	1
81	3	1	7
82	6	1	9
83	1	1	9
84	9	9	1
86	5	9	6
87	2	1	1
90	8	9	9
91	9	9	9
92	9	9	7
93	1	1	1
94	9	9	9
99	9	9	2
103	1	9	1
104	1	1	6
105	9	9	9
107	1	5	7
108	1	1	9
109	1	9	9
110	1	1	9
113	9	9	9
115	1	1	9
118	9	9	9

Article Nr	METC	Informed consent	Follow-up
119	9	1	1
120	9	9	9
123	1	9	9
135	1	1	9
136	9	9	9
137	1	9	9
140	1	5	7
142	1	1	9
143	1	1	7
144	1	9	8
145	9	9	7
146	1	1	1
147	1	1	9
148	9	9	9
150	2	9	9
153	5	9	9
154	9	9	9
156	9	9	9
160	5	9	4
161	1	1	1
164	1	1	1
165	9	1	9
169	1	1	1
170	2	9	4
171	5	9	7
173	1	9	6
175	1	1	9
176	1	1	9
178	2	1	9
179	7	1	1
180	9	9	1
181	5	9	4
183	1	1	8
184	1	1	1
186	2	1	1
187	1	1	9
188	9	3	9
194	1	1	9
195	2	1	2
196	1	9	9
197	9	9	7
198	1	9	9
200	5	9	9
203	2	1	1
204	2	9	1
205	9	9	9
206	2	3	1
207	2	3	1
210	2	1	2
211	9	3	1
213	2	1	1
216	2	1	1

Article Nr	METC	Informed consent	Follow-up
219	2	1	1
220	2	1	1
225	9	9	9
227	1	9	9
230	9	9	1
232	2	1	9
234	9	1	1
242	1	9	9
244	1	1	9
246	1	1	4
247	9	9	9
248	2	1	1
249	9	1	1
250	2	1	1
253	2	1	2
256	7	1	1
259	9	1	1
261	2	1	9
262	2	1	9
267	9	9	9
268	9	9	9
269	9	9	9
270	9	1	9
272	9	9	9
273	9	9	9
275	2	3	1
276	5	9	9
279	7	9	9
281	2	1	1
283	2	1	1
284	2	1	1
285	9	9	9
286	2	1	1
288	2	1	2
291	2	1	1
294	1	4	9
295	2	1	1
297	2	9	1
298	2	1	1
301	2	1	1
303	2	1	2
308	2	1	9
311	9	9	1
315	2	1	2
316	2	1	2
317	2	1	9
318	2	1	1
319	9	9	9
323	2	1	1
324	2	1	1
328	2	1	9
330	2	1	9

Article Nr	METC	Informed consent	Follow-up
332	2	1	1
333	2	1	2
335	2	1	1
340	2	1	3
341	2	1	1
342	2	1	1
343	2	1	1
344	2	1	1
345	2	1	1
346	9	9	9
347	2	1	1
349	2	1	1
350	2	1	1
351	2	1	1
352	2	1	1
353	9	9	1
357	2	1	9
359	2	1	9
361	2	1	1
362	2	1	9
363	2	1	9
364	2	1	9
365	5	9	9
366	9	9	7
367	2	1	9
370	1	1	9
371	2	1	1
372	2	1	3
373	2*	1	9
374	2	1	1
376	2	1	9
378	2	1	1
380	2	1	9
381	2	1	1
382	2	1	9
384	9	9	9
390	2	1	9
392	9	9	3
393	2	1	9
397	9	9	9
400	2	1	3
402	2	1	2
403	9	9	9
404	9	9	9
406	2	1	9
407	2	1	1
412	2	1	2
413	2	1	9
417	9	9	9
418	9	9	9
419	2	1	2
420	2	1	9

Article Nr	METC	Informed consent	Follow-up
422	2	1	2
424	2	1	9
429	9	9	9
431	2	1	9
432	9	9	9
434	9	9	9
437	2	1	9
444	9	9	3
446	9	1	9
448	9	9	9
449	9	9	9
454	2	3	9
457	9	9	9
459	2	9	9
462	9	9	3
465	9	9	9
466	9	9	9
468	7	1	9
470	9	9	9
477	7	1	9
481	2	1	1
482	7	1	9
483	7	1	9
484	7	1	3
485	7	1	3
487	2	1	3
488	7	1	9
489	7	1	9
490	2	1	9

* In this case the protocol and approval were found in the METC archives

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- 3. De Nederlandse Gedragscode Wetenschapsbeoefening, Principes van goed wetenschappelijk onderwijs en onderzoek, Vereniging van Universiteiten VSNU, 2004, herziening 2012 (Dutch Code of Practice for Science, Principles of correct scientific research and education, Association of Universities in the Netherlands VSNU, 2005)
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- 6. Dutch legislation:
- Wet op de geneeskundige behandelingsovereenkomst (WGBO) (the Medical Treatment Contract Act)
- Wet medisch-wetenschappelijk onderzoek met mensen (WMO) (the Medical Research involving Human Subjects Act)
- Archiefwet (Public Records Act)