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Decision regarding research misconduct

Decision

The National Board for Assessment of Research Misconduct ("the Board") finds [redacted] and [redacted] guilty of research misconduct.

Background

On 20 July 2022, a case of alleged research misconduct was reported to the Board by [redacted] and [redacted].

The research concerns trachea transplantation. The article presents the follow-up of a transplant of a donated trachea. The operation was performed in Barcelona, Spain.

The report relates to allegations of fabrication and/or falsification in the following:

1. [redacted] (2014). The first tissue-engineered airway transplantation: 5-year follow-up results. *Lancet* (London, UK), 383(9913), 238–244. https://doi.org/10.1016/S0140-6736(13)62033-4.

   The allegations relate to falsification by omission of key information in several places in the article, regarding insertion of a stent in the transplanted trachea within four months after the operation. In addition, instances of falsification are said to be found in three figures (4, 5 and 6C) failing to show what it is claimed that they show.

The authors whose names are underlined conducted the research at a Swedish entity responsible for research.

Respondents' statements

The respondents have been offered several opportunities to express their views in the case, but have chosen not to do so.

Expert statement

The Board has obtained an expert witness's opinion on the matter. This expert[1] has had the task of assessing whether the article contains fabrication and/or falsification and whether, if so, this constitutes a serious breach of good research practice.

The expert's assessment is that important items of information emerging from the various examinations of the patient have been omitted in several places in the article, and that this constitutes falsification. In the article it is asserted that the results show that the transplanted trachea was safe; this too, in the expert's opinion, is falsification. Finally, he deems that the three figures concerned in the allegations involve falsification.

According to the submitted report, a stent was placed in the patient's trachea three weeks after the transplant because the trachea collapsed. The article states that a stent was not necessary until after six months. This assertion in the report is supported by a letter[2] from [redacted] at the hospital in Barcelona where the patient was followed up for nine months after the operation by [redacted], his colleagues and others. The letter was published in *The Lancet* in 2019, which was six years after the article in question was published online in *The Lancet*. In email correspondence from 2018[redacted], the current director of the clinic in Barcelona, has confirmed to one of the complainants that a stent was inserted in the patient's trachea three weeks after the operation. When [redacted] was contacted about this information during June-July 2023, however, he stated that he had checked the patient's medical record again and was now unable to find information that a stent had been inserted so soon after the operation. According to him, the medical record documents the performance of a bronchoscopy three weeks after the operation and records that a stent was not inserted until 10 October 2008, which was less than four months after the transplantation.The expert explains that the uncertainties surrounding when a stent was placed in the patient's trachea mean that there are uncertain points regarding exactly which information in the article is correct. This applies to the sections describing results from various examinations at regular intervals after the transplantation. Besides the absence of a statement that a stent was inserted at any time prior to six months post-transplant, the results of the examinations should also vary, depending on when the need for a stent arose and when the stent was placed in the trachea. The expert gives examples of several passages in the summary, results and discussion sections that he considers to be scientifically incorrect and to constitute falsification, even when a stent was inserted on the later occasion, just under four months after the operation. The incorrectness applies, for example, to the assertions that no complications had arisen after four months, but also to what may be expected from testing a patient's pulmonary function at various times.

The expert has investigated the figures under suspicion and compared them with figures that have been published or presented on other occasions. His conclusions are

[1] Professor Peter Naredi, Institute of Clinical Sciences, University of Gothenburg.
[2] Molins L. (2019). Patient follow-up after tissue-engineered airway transplantation. *The Lancet* (London, UK), 393(10176), 1099. https://doi.org/10.1016/S0140-6736(19)30485-4.

that Figure 4 is Figure 3E from [redacted] et al. 2012,[3] rotated and mirrored, and that Figure 5 is the same as Figure 3L in [redacted] et al. 2012. Figure 6C, he believes, is duplicated from [redacted] et al. 2010,[4] Figure 1L. The figures in the previous publications are, according to the expert, derived from examinations carried out on patients other than the patient whose follow-up is presented in the article concerned. The expert's conclusion is therefore that the figures do not show what they said to show in the article, and that they are therefore falsified.

Legal regulation

Under the Act (2019:504) on responsibility for good research practice and the examination of research misconduct ("the Act"), the Board is tasked to investigate issues of research misconduct.

Section 2 of the Act defines research misconduct as a serious breach of good research practice in the form of fabrication, falsification or plagiarism, committed with intent or through gross negligence, in the planning, conduct or reporting of research.

The Board's assessment takes place in stages, pursuant to the above provision.

Grounds for decision

Research covered

Section 3 of the Act covers research conducted by higher education institutions that have the Swedish state as the entity responsible for their research, and that are subject to the Swedish Higher Education Act (1992:1434), other government agencies, municipalities and regions and certain other specified activities.

[redacted] and [redacted] made their contributions to the research reported at Karolinska Institute, an entity responsible for research, that is subject to Section 3 and, accordingly, investigation by the Board.

[redacted] and [redacted] carried out their part of the research at foreign entities responsible for research. As such, they are not subject to Section 3 and are not investigated by the Board.

[3] [redacted] (2012). Engineered whole organs and complex tissues. *The Lancet* (London, UK), 379(9819), 943–952. https://doi.org/10.1016/S0140-6736(12)60073-7 (Retraction published in *The Lancet*. 2018 July 7;392(10141):11.)

[4] [redacted] (2010). Tissue engineered human tracheas for in vivo implantation. *Biomaterials*, 31(34), 8931–8938. https://doi.org/10.1016/j.biomaterials.2010.08.005.

Planning, conduct or reporting of research

As defined in Section 2 of the Act, breaches of good research practice that may constitute research misconduct must have been committed during the planning, conduct or reporting of research. This means that the term "misconduct" refers to breaches throughout the research process.[5] "Reporting" refers both to publication and to other types of disclosure.[6]

The Board considers that the case relates to reporting of research because the allegations concern wording in an article that is published in a scientific journal.

Fabrication, falsification or plagiarism

The Board's remit is to investigate three forms of research misconduct: fabrication, falsification and plagiarism. These terms are not defined by law, but the preparatory work for the Act refers to the fact that they are described in codes (codices) and guidelines on research ethics, such as *The European Code of Conduct for Research Integrity*.[7,8]

Fabrication means that the researcher invents results and documents them as if they were genuine.

Falsification refers to manipulation of research material, equipment or processes or unjustified alteration, omission or suppression of data or results.

The complainants' opinion is that the article contains falsification through omission of information that a stent was inserted in the patient's trachea within four months after the operation. In addition, the complainants suspect that three figures are falsified because they are duplicated from other publications.

The expert's assessment is that the article contains falsification in several places in the text, for example omission of the statement that a stent had been placed in the trachea earlier than six months after the transplant. In addition, the results of the various examinations must have been altered if a stent was placed in the trachea within the first four months. According to his assessment, too, the three figures have been falsified.

The current director of the clinic where the operation was performed, and where the patient was followed up for nine months after the operation, [redacted], has stated to the Board that the patient's medical records contain information that a stent was inserted in the patient's windpipe less than four months after the operation. The Board finds that information on these matters has been omitted in the article, which states that "4-month follow-up showed no complications" and that "The graft behaved as expected until 6 months after surgery." The Board considers that the notion of "no complications" is misleading and that omitting information that a stent was inserted

[5] Swedish Government Bill 2018/19:58, p. 100.
[6] Swedish Government Bill 2018/19:58, p. 49.
[7] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, section 3.1.
[8] Swedish Government Bill 2018/19:58, pp. 45, 100.

constitutes falsification. In addition, the Board considers that the above quotations mean that information was invented, which entails fabrication. The Board shares the expert's assessment that Figures 4, 5 and 6C do not show what they are said in the article to show. The figures are therefore deemed to be falsified.

Serious breach of good research practice

> Only serious breaches of good research practice can constitute research misconduct.
>
> In principle, fabrication and falsification are always serious breaches of good research practice.

According to the expert's assessment, these falsifications constitute serious breaches of good research practice.

The premise of the Board's assessment is that fabrication and falsification are, in principle, always serious breaches of good research practice. No reason to deviate from this premise has emerged in the case. Accordingly, the Board's conclusion is that the breaches constitute serious breaches of good research practice.

Intent or gross negligence

> Since 1 January 2020, researchers' responsibility to comply with good research practice in their work has been subject to statutory regulation under Section 4. The potential or required extent of such responsibility must be examined and assessed in each individual case.
>
> Under Section 2 of the Act, for research misconduct to be found, the serious breach of good research practice must have been committed with intent or through gross negligence.
>
> "Intent" means that the researcher understood what (s)he was doing, while "negligence" means that the researcher, in any case, should have understood this.
>
> "Gross negligence" requires the conduct to stand out as particularly serious or reprehensible. According to the preparatory work, oversights, carelessness or misunderstandings should not, as a rule, be regarded as gross negligence.[9]

As clarified above, the article contains fabrication and falsification in several places, and three falsified figures (4, 5 and 6C). [redacted] was the surgeon in charge of the operation, the project leader for the research project and the corresponding author of the article. The article states that: "The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit for publication."

Considering this background, the Board's assessment is that [redacted] knew that a stent had already been inserted within four months of the operation, and that he thus knew that the article contained erroneous descriptions. [redacted] is also

[9] Swedish Government Bill 2018/19:58, pp. 50–51, 100.

the corresponding author of the two articles containing the originals of Figures 4, 5 and 6C and, as such, should thus have known their origin. The Board considers that he intentionally duplicated the figures and described the follow-up of the patient's state of health at different times incorrectly.

According to international guidelines,[10,11] all the partners in a collaboration must take responsibility for the integrity of the research. They also state that all authors are fully responsible for the content of the publication unless otherwise stated. Swedish law is based on this international regulation.

The purpose of the article is to describe the course of a patient's state of health over time, up to five years after the operation. [redacted] and [redacted] have refrained from expressing their views in the case. It is not evident from the article that they had limited expertise or limited responsibility that might justify their not being responsible for the whole content of the article. The Board also notes that both are co-authors of one of the articles, which contains the originals of the falsified figures. The Board's assessment is that [redacted] and [redacted] acted at least with gross negligence, if not with intent, when they failed to notice that the article contains incorrect information, that key information has been omitted and that several figures do not show what they purport to show.

Summary of the decision

Summing up, the Board finds [redacted] and [redacted] guilty of research misconduct.

The Board has made a decision on this matter, following a presentation by Sofia Bergström, caseworker.

Catarina Barketorp
Chair

Sofia Bergstrom
Caseworker

[10] *The European Code of Conduct for Research Integrity*, revised edition. Berlin: All European Academies (ALLEA); 2018, 2023, Chapter 2.6.

[11] *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly work in Medical Journals.* Updated May 2022, International Committee of Medical Journal Editors. https://www.icmje.org/recommendations.