



UvA-DARE (Digital Academic Repository)

Good science at heart

Lessons on ethics from big data research in sudden cardiac arrest

Bak, M.A.R.

Publication date

2021

[Link to publication](#)

Citation for published version (APA):

Bak, M. A. R. (2021). *Good science at heart: Lessons on ethics from big data research in sudden cardiac arrest*. [Thesis, fully internal, Universiteit van Amsterdam].

General rights

It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations

If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: <https://uba.uva.nl/en/contact>, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

7 | Publishing case reports of deceased patients

One of the first portraits he painted was of Dr Gachet, who immediately felt great sympathy for Vincent. They spent most of their time together and became great friends - a friendship not ended by death, for Dr Cachet and his children continued to honour Vincent's memory with rare piety.
(Jo van Gogh-Bonger, *Memoir of Vincent van Gogh*. Dec 1913)

Summaryⁱ

Publishing a patient history or case report fulfils an important role in education and scientific research. However useful this may be, proper privacy protection is an elementary prerequisite. The main rule is that it must be nearly impossible to identify a patient in the presented case. If complete anonymity is not a possibility, or if this is doubtful, then publication is only possible after the patient's informed consent. But what if such authorization is not possible after a patient's death, or upon their departure to an unknown destination? We believe that it still should be possible then to publish patient cases, however, only if this is decided on after careful consideration of all interests, including those of the next-of-kin.

7.1 Introduction

It can be of great value within medicine to publish interesting medical case histories in scientific journals. The Dutch Journal of Medicine (*NTvG*), for example, contains a section "Clinical Practice" that offers authors the opportunity to highlight striking or rare case histories of one or more patients, for example presented as a clinical lesson, dilemma or new insight. The question is which rules apply to the publication of such case descriptions (see example in Box 7.1). Should consent always be sought from affected patients, and if so, what to do if they have since died or if no contact details are available, for example due to moving to an unknown destination? Almost 30 years ago a discussion arose about the publication of data from the medical file of Theo van Gogh, who died in 1891, and of his brother, painter Vincent.^{1,2}

ⁱ This chapter was published as: Ploem MCP, Bak MAR, Linthorst GE. Casuïstiek van overleden patiënten: kan die zomaar gepubliceerd worden? *Nederlands Tijdschrift voor Geneeskunde*. 2021;165:D5685

In our contribution, we discuss the rules for publication of a patient case, with special attention to the situation in which the person concerned can no longer give permission as a result of death or the lack of contact details. We believe this fulfils a need among authors of such case descriptions, but possibly also among journal editors.

Box 7.1 Case

You work as a specialist in a general hospital. During your shift, a 54-year-old man is admitted with a ketoacidotic disorder of a recently diagnosed diabetes mellitus in an already known neuroendocrine tumour. A few weeks earlier, the patient started treatment for his diabetes. Despite rapid intervention, ventricular fibrillation develops shortly after admission and the subsequent resuscitation is unsuccessful. In autopsy, no additional explanation for the sudden death is found in addition to the known neuroendocrine tumour. You therefore wonder whether the chosen diabetes treatment in patients with a neuroendocrine tumour can lead to such a serious ketoacidotic disorder and decide to write an article about this. Your preference is for a description of the patient case in question to be as detailed as possible, and you believe that this is possible if you ask the next of kin (partner and/or children) for permission. Is this right?

7.2 Main rules for the publication of patient cases

The most important rules for the publication of patient cases arise from privacy legislation, namely the General Data Protection Regulation (*AVG*) and the Medical Treatment Act (*WGBO*) in the Netherlands. What rules for publishing a deceased patient's case can be derived from this?

7.2.1 Anonymization or consent

When publishing the results of scientific research, but also when presenting a clinical lesson for education, it has always been the case that this is preferably done in a way in which the patient remains completely anonymous.³ If this principle can be met, the said legislation does not apply. The latter simply means that the legislation does not impose any further requirements on the publication of a case, such as asking for permission. The problem, however, is that it is becoming increasingly difficult to completely anonymise a case given the growing amounts of available data and technological progress. For example, when a case mentions a rare genetic variant or disease that has been diagnosed in the person concerned. It follows from the GDPR that a case description that does not contain directly traceable patient data, but from

which a patient can be recognized through spontaneous recognition or linking of data, cannot usually be considered anonymous. It is only possible to speak of a 'GDPR-proof' anonymization if it is no longer reasonably possible – that is to say without disproportionate use of manpower, time and resources – for someone other than the researcher to identify the patient from the case.

When (full) anonymization is ultimately not an option, for example because the case study would lose its function in the article by omitting certain details, or when there is doubt as to whether the requirement of complete anonymization can be met, the authors must ask the patient for permission for publication of the case. This permission must be free and can therefore be refused without any problems, but does not have to be given in the form of a signature in order to be legally valid: a note in the medical file or a registration intended for that purpose is sufficient, as long as it can be demonstrated that the person concerned has consented, when the journal requests this. A signature is, incidentally, the standard required by most scientific journals.⁴ The consent requirement, which applies to non-anonymous publication, remains in force after the patient's death. This follows from the medical confidentiality that 'reaches beyond the grave'. In other words: not publishing a case (completely) anonymously also means a breach of professional secrecy after the patient's death, for which the patient should in principle have given permission.

7.2.2 Problem with deceased patients

What to do now if a researcher comes up with the idea to publish about a specific case only after the death of the person concerned. Is it sufficient to ask the next of kin for permission, as the researchers in our case did? Some journals such as the British Medical Journal ask for the consent of next of kin, but we consider this neither sufficient nor necessary.⁵ Of course it is important to check how relatives view non-anonymous publication and whether they are aware of any wishes of the deceased, but from a legal point of view, at least under Dutch law, their consent cannot replace that of the deceased. Moreover, from a moral point of view, it may not be desirable in all cases to approach next of kin about this: consider, for example, parents who have recently lost a child.

Does it stop there? That is to say, can an important, but not (completely) anonymous case of a deceased person never be published without their prior consent given during their lifetime, even if the person concerned died decades ago? That point of view is too demanding for us. Earlier in this journal it was stated that the passage of time after death has a certain 'eroding' effect on the duty of confidentiality, in the sense that the importance of secrecy may diminish as time goes on, while other interests, such as scientific or educational importance of publication of special or exemplary case studies, gain in authority.^{6,7} We believe that this erosive effect of time only comes into effect when at least one generation has passed since the death of the

patient. In many countries a period of 50 or 70 years applies after death (or sometimes even 100 years in view of the increased life expectancies) in order to be able to speak of an 'elaborate duty of confidentiality': this corresponds respectively to the time periods for public access to death certificates and copyright expiration in several countries.⁸

Our position is therefore that in special situations there must be room to deviate from the consent rule. A prerequisite is then that complete anonymization of the case is not an option and that the interests at stake in the specific case have received careful consideration. This statement also follows from the COPE guidelines of the International Commission for Publication Ethics.⁹ In making that assessment, we believe that the researcher who wishes to publish, or the body that supervises publication, should take into account at least the following factors:

- a) the period that has elapsed after the death of the person concerned (the longer, the better);
- b) the scientific interest served by the publication of the case in not completely anonymised form;
- c) the sensitivity of the data being published;
- d) any indications that the data subject would have objected to this;
- e) the wishes of the surviving family members of the person concerned, after being informed of the intention to publish a traceable publication.

7.2.3 Evaluation of our case

In the case described earlier, there is at least some doubt about whether the case can be published anonymously. Therefore, it should be assessed whether publication is acceptable on the basis of the above criteria. The course of time does not play a significant role in the case. Therefore, the researchers must first be able to demonstrate that publication of the case in a possibly identifying form is necessary for the medical-scientific interest to be served. In this case, that interest may reside in the fact that an undesirable side effect of medication is suspected in a patient with a rare condition. In addition, if the family situation permits, the researchers will have to contact the partner and/or children to find out on the one hand whether the patient himself might have objected to publication, and on the other hand how they themselves view it. If the researchers come to the conclusion on the basis of the foregoing, possibly advised by an ethics committee, that publication of the case is acceptable, it is of course up to the editors of the scientific journal concerned to assess whether they also want to be accountable for publication.

7.2.4 When the patient is no longer traceable

A more or less comparable situation arises if a researcher wishes to publish a medical history of a patient who can no longer be traced when consent was not granted by this person at the time. In our opinion, also in these circumstances, publication of a case that is not (completely) anonymised should not be entirely excluded in advance. At the same time, in this context one should expect an even stricter assessment against the above criteria. In addition, it must be established that the investigator made reasonable efforts to determine the patient's whereabouts.

7.3 Conclusion

Researchers who want to publish a patient's case after the death of the patient, are faced with a problem when the scientific or educational value of the case description would be lost if the case is to be fully anonymised. After all, it is no longer possible to request permission from the data subject, as required by professional secrecy. This also applies when the patient is no longer traceable. However, the fact that it is no longer possible to ask for permission does not necessarily mean that the road to non-anonymous publication is hermetically closed. Provided that a decision to do so by a researcher and approval of this by a journal editorial team has followed a careful consideration of all the interests at stake (including those of the next of kin) in the specific case, we believe there should be some room for publication. Because such considerations will not be easy, it is worth considering asking an ethics committee for advice in this regard.