

Post mortem scientific sampling and the search for causes of death in intensive care: what information should be given and what consent should be obtained?

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Abstract

Purpose

The search for cause of death is important to improve knowledge and provide answers for the deceased's relatives. Medical autopsy following unexplained death in hospital is one way to identify cause of death, but difficult to carry out routinely. Post mortem sampling (PMS) of tissues via thin biopsy needle or "mini incisions" in the skin may be a useful alternative. We aimed to assess how this approach is perceived by intensive care doctors, and secondarily, to evaluate how this practice is considered in ethical terms in France.

Methods

Study of PMS practices immediately after death in 10 intensive care departments. The medical director of each centre was interviewed by phone and asked to describe practices in their unit and identify questions raised concerning this practice.

Results

PMS is routinely performed in 70% of units, without obtaining formal consent and without precise rules for communicating results. Approaches to PMS differed between centres, but all physicians felt that PMS is useful, firstly for the scientific information provided, but also for the information it provides for relatives. All physicians regret the lack of standards to structure PMS practices.

Conclusion

Information from post-mortem examination is important for society, to inform about causes of death; for doctors, to improve practices; and for decision-makers responsible for organising care. Debate persists regarding the balance between individual rights and community interests. We purport that an approach for identifying cause of death could easily be integrated into the relationship between carers and relatives, provided full transparency is maintained.

MESH Keywords Adult ; Autopsy ; ethics ; psychology ; statistics & numerical data ; Cause of Death ; Family ; psychology ; France ; Hospital Mortality ; Humans ; Informed Consent ; ethics ; psychology ; Intensive Care ; Middle Aged ; Tissue and Organ Harvesting ; ethics

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INTRODUCTION AND OBJECTIVES

One of the major preoccupations of doctors, beyond patient care, is identifying the reasons for the death of a patient. The search for a cause of death is important, to provide answers to the inevitable questions from close relatives of the deceased. The search for the cause of death is also important to broaden knowledge, particularly in deaths where the cause of death is unclear, with a view to improving diagnostic and therapeutic strategies, and more generally, quality of care.[1 –4]

This approach is one of the missions of public health and may contribute to changes in health policy in terms of care and prevention. It should improve our understanding of the causes of death, and such improvements are necessary for the compulsory rigorous completion of the section devoted to cause of death on death certificates. This section is used to compile national statistics every year.

In the setting of intensive care, progress in diagnostic techniques (imaging, endoscopy, biological tests etc.) performed while the patient is alive has considerably reduced uncertainty in this area. However, the causes of death or the circumstances leading to death in

intensive care may often remain unexplained or unclear.[5 –11] This is a particular problem in intensive care, because the extensive technological interventions may mask physiopathological conditions, or even generate new ones, thus creating new and more complicated causes of death.[12 ,13] A recent study of 167 autopsies carried out between 2001 and 2003 in a non-surgical intensive care unit in Paris identified a large number of cases of mistaken diagnosis, with a major difference between medical diagnosis and the cause of death identified on medical autopsy in almost 32% of cases.[14] Another study demonstrated that, for deaths occurring in the 10 days following admission, the autopsy revealed discrepancies between the clinical diagnosis and the actual cause of death.[15] Finally, Weustink *et al* [16] recently showed that combining post-mortem MRI and CT scanning with ultrasonography-guided necropsies (a procedure they named ‘minimal invasive autopsy’) enabled the cause of death to be identified or confirmed.

Medical autopsy following an unexplained death in hospital is recognised as one way to identify the cause of death. However, systematic autopsy is difficult to carry out in practice, due to organisational and ethical problems.[17 ,18]

Nonetheless, the need to know the real cause of death often persists, both for the medical staff and for the relatives. The lack of post mortem examination is an integral component of this debate. Indeed, the information provided by autopsy can assist in the mourning process, and may have medical implications for the relatives. Post mortem sampling (PMS) of tissues by the intensive care doctor, by means of a fine biopsy needle or via ‘mini incisions’ in the skin, may make a useful contribution to the search for the cause of death.[19 –21] Such samples can only be taken from certain easily accessible organs (most frequently the liver and lungs, or more rarely, the kidneys) and result in only small, discreet breaks in the skin. They could never entirely replace a conventional autopsy [19], as they do not provide morphological or macroscopic information. However, they are easy to carry out and appear less traumatic, and they may therefore be more acceptable to professionals and seen in a better light by relatives.

Aside from these hypotheses, even though PMS may have the same goals as autopsy (etymologically, “seeing for yourself”), the questions raised by the implementation of such an approach must be discussed with a view to structuring this practice, if it is to develop in the future. This approach would integrate into a continuum of care for the person, extending from life into death.

In France, the so-called bioethics laws of 2004 [22] are based on the principle of presumed consent for sampling from corpses, namely that samples may be taken for scientific or therapeutic purposes as long as the patient did not object to such sampling during their lifetime. Such objections can have been recorded in the national registry of refusals, or may be reported by relatives. However, these procedures for recording refusal seem to have been thought out with an eye to traditional medical autopsy on the one hand, and organ donation on the other. It remains unclear whether they are relevant to PMS.

We therefore carried out a study in a selection of intensive care departments, to evaluate, firstly, how this approach was perceived by intensive care doctors, and secondly, how this practice could be considered in ethical terms in France.

METHODS

We carried out a study on the practice of tissue sampling immediately after death in collaboration with adult intensive care departments. This study aimed to identify the ethical questions raised by intensive care professionals engaged in this emerging practice. Key questions posed concerned access to the corpse, the question of consent that this access entails, and the wider issue of informing the relatives. Thirty two French intensive care departments were initially contacted by email (16 university teaching hospitals, and 16 non-academic general hospitals). In total, ten centres accepted to answer (4 university hospitals, 6 general hospitals representing 6 medical and 4 surgical intensive care units).

The medical director of each centre participating in the study was contacted and asked to describe the practice of this technique in their department.

RESULTS

Questions raised in practice

Frequency, indications and technique

All 10 participating centres were interested in identifying the cause of death. Seven centres performed post-mortem sampling. The other three did not carry out PMS as they were able to carry out conventional autopsy.

None of the centres systematically carried out PMS for every death and none could cite the precise frequency of these acts. However, the clinical conditions leading to this type of sampling were clearly identified and the reasons were identical in all cases, namely PMS was performed if the death was unexplained or the circumstances leading to the death were unclear. The scientific value of this approach was always cited. Three departments indicated that PMS improved their evaluations of morbidity and mortality, particularly as autopsy was not always possible. In cases of potential conflict in which the responsibility of the doctor might be invoked, all the doctors called for medico-legal autopsy rather than carrying out a medical autopsy or PMS.

Samples of lung, liver and kidney were usually taken. Liver and kidney samples were taken with a fine biopsy needle passed through the skin without the need for an incision. Lung samples were taken with a fine needle or surgically, with the creation of a small skin incision.

Most of the doctors informed the personnel present of the reasons for which PMS was carried out and explained that the performance of such procedures should be taken into account in the overall management of the deceased. They recognised that it was essential to inform the care team, because this practice slightly delays the preparation of the body for viewing and the admission of the patient's family to the room.

All post mortem samples were sent to the pathology laboratory or the microbiology laboratory, as appropriate. None of the specimens were kept in the department or in a tissue library in the laboratory for an extended period. The samples were studied under the same conditions and in the same time frame as samples taken from living patients.

Questions relating to routine application of PMS

Only one department had a written protocol for PMS. None of the departments considered this practice to be a research protocol. Most considered it to be a continuation of general care, part of the diagnostic process and good medical practice. Consistent with this view, none of the centres felt that it needed to be covered by the French law on biomedical research or submitted to an institutional review board for approval.

Prior information and consent

Three centres declared that they informed relatives before performing PMS. The reasons given for informing the relatives were similar in all cases: obtaining explicit consent from the family (rather than views concerning the patient's wishes), with a view to achieving transparency and helping the relatives to deal with this procedure being carried out. The information given always clearly stated that the appearance of the body would be preserved.

The doctors stated that this information was well received by relatives, whose perception of this medical approach was favourable. Relatives accepted PMS because they wanted to understand and know the cause of death. The fact that the patient's body was not violated contributed to increasing relatives' acceptance.

One centre consulted the national register of refusals before meeting relatives, to determine whether the patient had objected to medical autopsy during his or her lifetime. This department extrapolates this information, to establish an analogy between medical autopsy and PMS.

The centres that did not inform the relatives cited as justification the painful experience of asking permission from the family, and the fact that seeking consent from the family does not legitimise the procedure, since the relatives' opinions do not necessarily reflect the patient's wishes. They also highlighted the lack of any legal obligation to seek consent from the family.

Communicating the results

The results were systematically communicated to the relatives by six of the seven centres that carried out PMS. For these centres, providing the results was an integral part of a policy of transparency with respect to the relatives, and contributed to the continuity of management.

The only centre that did not systematically inform families of the results cited the mainly scientific motivation for the sampling and the absence of a direct benefit to the deceased or their family.

All the centres that informed the family before taking samples recognised that this initial communication made it easier to provide additional information subsequently.

Concerning the nature of results communicated and the respect of medical confidentiality, the families were provided with any results that could have a potential impact on the health of relatives, as well as results that contributed to a better understanding of the reasons for the patient's death. These centres said that they communicated the results for reasons of transparency. Some of the centres questioned therefore stressed the need to adapt the information in order to respect medical confidentiality and the interests of the relatives on a case-by-case basis.

DISCUSSION

Autopsy has contributed to the advancement of medical knowledge. Elements from the post-mortem examination of a body are important for society, which needs to be informed (and/or enlightened) about the causes of death of its members, not only for doctors, to

help them to improve their practices, but also for the decision-makers responsible for organising care. Medicine is a social practice that aims to cure the individual and to meet the objectives of public health, notably through the duty of the doctor to understand the causes of death. Thus, in any approach to post mortem diagnosis, there is a debate about the balance between respecting the rights of the individual and the interests of the community.

Our study shows that samples are taken as a matter of course as part of the care process, without formal consent being sought and without any precise rules concerning the communication of information. Weustink *et al* [16] mention that informed consent was obtained, but do not explain at which timepoint, or from whom it was obtained. In France, obtaining consent for autopsy from a patient on admission to intensive care is felt to be contrary to the psychological well-being of the patient, as this request raises the possibility of death. Resorting to the alternative principle of presumed consent would require that all citizens be aware of this issue, making it possible for them to object by formally recording their refusal while still in good health.

If PMS were to become common practice in the future, all those concerned (doctors, representatives of civil society, patients' associations) should discuss the regulations required. This question will be particularly important when bioethics laws are to be updated [22]. These laws do not currently consider the issue of PMS in France.

Consent

The legitimacy of PMS is important from a medical, scientific and societal point of view, but the right of the individual to make his or her own decision in this domain must be taken into consideration.

Presumed consent, a principle initially developed for organ donation in France, is sometimes taken as a reference for PMS. According to this principle, it is presumed that, in the absence of any objection made during the lifetime of the patient, samples can be taken. Objection to sampling can be made in two ways in France:

- By informing relatives, who can then provide information about the wishes of the deceased (but should not express their own point of view).
- By recording their objection in the national registry of refusals, maintained by the National Agency of Biomedicine, under the responsibility of the Ministry of Health.

This principle, with the interests of the community as the overriding factor, could serve as a reference for PMS. Indeed, PMS is also in the best interests of the community: a better understanding of the causes of death advances medical knowledge, leading to better care and organisation in intensive care departments. However, for the sake of consistency, the national registry of refusals should include a specific right to object to PMS, by distinguishing between PMS, medical autopsy and organ or tissue donation.

The wording in the registry of refusals currently reads: 'I object to the donation of my body for medical research regarding the cause of death (autopsy, except forensic autopsy, to which objection is not possible)'. [23] PMS is therefore neither recognised nor specifically taken into account in this approach to refusal. In addition, no specific information program concerning the unknown topic of PMS has been developed for the general public. The rule of presumed consent, applied in the present context of a complete lack of information of the public, does not appear to be ethically acceptable as regards respect for the freedom of choice.

A possible alternative model is that of explicit consent during the patient's lifetime, following information of the general population at precise moments in the life of an individual (for example, when obtaining a driving licence or taking out health insurance). Indeed, a system based on explicit consent has been widely adopted internationally, particularly for organ donation. For example, in most Canadian provinces, people can voluntarily sign a register during their lifetime to give consent for subsequent organ donation. [24] Adopting this approach in France would mean abandoning the principle of presumed consent in favour of a system in which individuals have more autonomy and must explicitly commit themselves. Indeed, it should be stressed that the principle of 'presumed consent' is not in line with a society in which there is increasing emphasis on the right of patients to make free and informed choices on all aspects related to their health. [25] Another argument in favour of explicit consent is the dependence of this approach on the education of citizens and positive solidarity, contrasting with implicit consent, which may conceal a lack of knowledge or misunderstanding. However, the choice of a system based on explicit consent would require public authorities to organise themselves so as to reach all citizens, to increase awareness and ask people to make their choices known. This would represent a democratic choice with repercussions for the organisation of the public sector and budget decisions.

A third model would involve consulting the relatives of the deceased (unless the deceased had made specific provision for this situation whilst still alive) because, although the body does not legally belong to the relatives, they are responsible for managing the death and the funeral rites. The relatives are in fact trustees responsible for organising the funeral and respect of the body, based on the beliefs of the deceased. They may therefore be considered legitimate representatives of the deceased, able to agree to or to oppose the removal of

samples. This approach also fits into a more general framework of autonomy of the individual, and favours the choices of individuals and their families. It makes it possible to take into account the psychological status of mourning relatives and the religious dimension, which may include the need for an intact body.[26 ,27] However, one of the problems of this approach is that it may not necessarily reflect the choices or wishes of the deceased.

A fourth and final approach can also be considered, in which there is no need for specific consent, PMS being considered as a legitimate extension of the intensive care process. This approach is consistent with the missions of public health and would in the best interests of society, where improvements in medical knowledge are for the greater good. In some medical or socio-medical fields, individual autonomy is relative or overridden, in a social contract in which the interests of society have precedence.

Indeed, in some cases, the medical profession can overrule personal choice, in the name of solidarity and for the public good (e.g. vaccination programmes, medico-legal autopsies, compulsory notification and treatment of certain contagious diseases etc.). This last option, by allowing systematic PMS, appears to be the most suitable from an epidemiological and scientific point of view. PMS would then be complementary to the national survey of causes of death, which is based on death certificates.[28] These compulsory certificates are drawn up without the consent of the patients or the relatives, because they are simply considered to be of fundamental importance to the community. PMS could be viewed in a similar way: despite its limitations, this technique, with or without medical imaging, could increase our understanding and, in the long term, improve the care of patients admitted to intensive care departments. The use of such an approach would require public debate, as it entails an erosion of individual autonomy in favour of the interests of society. This approach would clearly involve the acceptance of a utilitarian dimension of medical science, with the aim of ensuring progress for the common good.

Informing the relatives

Information of the next of kin is possible, with no risk of violating medical confidentiality, in that French public health law permits the transmission of information enabling the relatives to 'understand the cause of death, preserve the memory of the deceased or exercise their rights, on condition that the deceased did not object during his lifetime'.

According to medical deontology, any information may be communicated to relatives, as long as it does not tarnish the image of the deceased. Healthcare professionals therefore need to prevent the transmission of medical results reflecting on the behaviour, personal and private life of the patient or of any other revelation deemed sensitive. In all other situations, the principle of transparency with respect to the relatives should prevail.[29] This approach should prevent the development of suspicions or difficult situations arising from unfortunate revelations. Transparency and dialogue are the foundations of confidence.

Information is fundamental because it satisfies several levels of need [30]. Firstly, it enables the family to determine whether the approach is of medical interest to the community or themselves (advantage of being aware of an inherited illness, death from a professional illness leading to a right to compensation etc.). Secondly, it provides an opportunity to explain to the relatives that they may, if they wish, receive information about the cause of death (unless the patient had expressly demanded that no information be communicated or if there is a risk of revealing information that might tarnish the image of the deceased). Thirdly, even if information is available, it may be of purely epidemiological interest only, and not of individual interest, apart from contributing to understanding the cause of death and thereby, aiding the process of mourning. Finally, it is important to understand and accept that the procedure may be of no consequence, and may provide no information whatsoever.

This information about the results is certainly one of the most important points. It is reasonable to think that providing this information may help distressed families, and contribute to establishing, maintaining, or even repairing a relation of confidence between relatives and doctors.[31]

If PMS provides new data, it may be possible to give some meaning to a death that would otherwise have remained unexplained. Removing doubts about the cause of death may help relatives to mourn. Clinicians have generally found that this approach may alleviate feelings of guilt in relatives who feel that they did not do enough for the patient or that they didn't seek help quickly enough, whereas in fact, the death was unavoidable in any case.

CONCLUSION

In the light of these findings, choices must clearly be made before PMS can be widely implemented. New standards, in addition to technical and scientific objectives, should take into account the issues identified. Thus, the idea that an approach to identify the cause of death could be seen as a necessary practice, carried out with full transparency, at a time when the clinical situation is deteriorating, could be integrated easily into the relationship between carers and relatives.

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