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The problem with medical research on tissue and organ samples taken in connection with forensic autopsies in France



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ABSTRACT

Currently, in France, it is legally impossible to conduct scientific research on tissue and organ samples taken from forensic autopsies. In fact, the law schedules the destruction of such samples at the end of the judicial investigation, and the common law rules governing cadaver research cannot be applied to the forensic context.

However, nothing seems in itself to stand in the way of such research since, despite their specific nature, these samples from forensic autopsies could be subject, following legislative amendments, to common law relating to medical research on samples taken from deceased persons. But an essential legislative amendment, firstly to allow the Biomedicine Agency to become authorized to issue a research permit and secondly, to change the research conditions in terms of the non-opposition of the deceased to said research.

Such an amendment would be a true breakthrough because it would allow teams to continue to move forward calmly in research, and allow this research to be placed within a legal framework, which would promote international exchanges.

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1. Introduction

As is the case in many medical specialties, research in forensic thanatology is fundamental to allow progress in the discipline. It seems essential to be able to access samples taken from the cadaver so as to better understand certain injury-based or mortal mechanisms and to attempt to answer forensic questions, at least in part. It is also necessary for teams to be able to build up collections.¹

This research can also be viewed from another angle: forensic autopsies account for 7000 -8000 autopsies per year in France. Fundamental research requirements are substantial and it would be worthwhile to be able to "use" the body as a possible source of samples for other studies, in order to understand the occurrence of a pathology or disease.

However in France, though its usefulness has been demonstrated, research in this specific field is difficult to undertake. Said research highlights two problems: the difficulty of performing

research on a deceased person, which falls within a strict framework, and the necessary compliance with the legal framework governing forensic autopsies. French teams often perform this research within a restricted legal framework, making the most of the legal vacuum in this activity. However, the forensic framework does not provide an exemption from compliance with the law on the protection of the cadaver, as witnessed by the recent ruling by the European Court of Human Rights, which recognized that tissue samples taken for purposes other than legal without the knowledge of the deceased person's wife during a forensic autopsy represented a breach of Articles 3 (degrading treatment) and 6 (right to respect for private life) of the European Convention on Human Rights.²

Forensic samples taken during autopsies for the purposes of the investigation and sealed are sometimes not used at all or not used in full. Thus it could be worthwhile using these samples for biomedical research once they are no longer required by the legal system, if said system has authorized the destruction of the sealed evidence.

Is this usage possible?

Consent is often at the heart of debates about the legal and ethical aspects of samples. When these samples concern the

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deceased person, this problem is even more difficult to solve. Some countries looked more extensively into the problems and drafted regulations.^{3,4}

However, the laws in place are very varied in terms of this requirement to obtain consent. $^{5-7}$

To answer this question for the France, it is useful to focus initially on what happens to forensic samples in France. We will then look into the possibility of performing biomedical research on these samples.

2. What happens to forensic samples taken during forensic autopsies in France?

2.1. The lack of legal provision before 2011

Inaccuracies concerning the status of samples from forensic autopsies can be explained by the fact that forensic autopsies were not covered by any legal provisions until 2011, apart from Article R.117 of the French Criminal Procedure Code regarding fees payable for such an examination.

As such, uncertainty surrounded the fate of samples from these autopsies. Moreover, in a ruling of April 28, 2009. The Court of Appeal of Toulouse noted that "there is no accurate legal provision on how samples taken from a forensic autopsy should be treated." What was to be done with this sealed evidence after the judicial investigation? Was it to be destroyed? Could it be returned to families who wished to have it?

The issue was really highlighted when families requested that these samples be returned to them. Could such a request be fulfilled? The French Public Health Code states that "anatomical parts of human origin destined to be abandoned must be incinerated" (article R.1335-11). However, given the claim laid upon them by families, they were no longer destined to be abandoned. As a result, it was difficult to justify subjecting these samples to the legal rules governing anatomical parts rather than returning them.

In the absence of a specific legal provision to this end, ultimately the judge was left to rule, and did so on many occasions (2002, 2009 et 2010).

He judged that "samples taken for analysis in connection with legal proceedings, whether from a living or deceased person, are not subject to restitution". The specific nature of these samples was highlighted as follows: "the restitution requested does not cover material objects, but human samples, which cannot be treated as ordinary objects". These are indeed "objects, but not ordinary objects". It is clear that this specific sealed evidence is not treated as ordinary sealed evidence, since it is not kept in the clerk's office, but instead at the forensic institute pursuant to the fact that its human character requires a specific method of conservation.

The last argument was that "samples taken from the human body for the purpose of forensic research to fulfill the requirements of an investigation or inquiry which cannot be subject to a right of ownership pursuant to Article 16-1 of the French Civil Code, are not seen as objects liable to restitution".

Following these recommendations, it was not until 2011 that the legislator acted, and a law was passed.

2.2. A legislative response since 2011

Article 147 of the law of May 17, 2011 "to simplify and improve the quality of law" added a chapter entitled "On forensic autopsies" to the French Criminal Procedure Code by way of Articles 230-28 to 230-31.⁹

The issue of biological sealed evidence is handled in it.

The law provides that "when biological samples taken during a forensic autopsy are no longer necessary to establish the truth, the competent judicial authority may order their destruction." (art 230-30 of the French Criminal Procedure Code). The legislator thus opted for destruction rather than restitution of these samples, in contrast to what was recommended by the Ombudsman.

Article 230-30 of the French Criminal Procedure Code therefore sets out the principle of destruction of biological sealed evidence, as long as said destruction is subject to authorization, and is ordered by the competent judicial authority (the public prosecutor, or the investigating judge). In principle, this authorization is given spontaneously, once the sealed evidence "is no longer necessary to establish the truth", in other words, when the investigation or judicial inquiry is complete.

Once the authorization for destruction is given by the judicial authority, a specific destruction procedure must be followed, according to whether or not the samples have been preserved in formaldehyde. It is necessary to follow the specific destruction procedure for infectious medical waste which is scheduled pursuant to the French Public Health Code.

Nevertheless, the law does provide for restitution in one specific case.

The law stipulates "however, subject to public health constraints, if these samples are the only elements allowing the deceased person to be identified, then the competent judicial authority may authorize their restitution for burial or cremation." (article 230-30 of the French Criminal Procedure Code).

In fact, restitution is only possible if the samples were the only elements allowing the deceased person to be identified. In practice, this situation occurs very rarely, for instance in the event of a plane crash in which only a few body parts are recovered. In such a case. these fragments are the only remaining elements of the deceased person, and it is easy to understand the importance their recovery has for families, allowing a funeral to take place. Furthermore, the Article states in this regard that in the event that restitution is possible, this may only be performed "with a view to burial or cremation." In fact, it is not a matter of conserving these samples at home, as a keepsake for example, but of holding a genuine funeral; in this context, the organ symbolically represents the entire body of the deceased person, and only in the case is restitution considered. However, in order for this to be possible, there must be no "public health constraints", that is to say restitution must occur under appropriate hygienic conditions, and must pose no risks, such as contamination.

Did the legislator provide for all the possibilities? It opted for destruction, but at no time was the possibility studied of performing biomedical research on these samples. However, is research not more useful than outright destruction? This hypothesis was not explored by the legislator given that the law was drafted to meet the needs of the families of deceased persons, and as such, all provisions were taken in consideration of them.

The question that arises is whether in the present context, it would be possible to conduct research on such sealed evidence. If so, what would the conditions for this research be? By imposing destruction at the end of the judicial investigation, has the legislator closed the door on such research on samples?

3. Scientific research on forensic samples from forensic autopsies in France

3.1. Scientific research on samples taken from cadavers is highly controlled but possible

In France, the Law of August 6, 2004¹⁰ now governs research on samples taken from a cadaver. It provides that "the removal of organs from a person whose death has been duly observed can only be

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