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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.[8] 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, 2004[10] 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*

performed for therapeutic or scientific purposes" (art. L. 1232-1 of the French Public Health Code).

The research on samples taken from deceased persons is possible, but it attaches certain conditions to that possibility.

3.2. Conditions of non-opposition

"[*Samples from a deceased person for scientific purposes] may be taken as long as the person did not make their opposition to such samples known during their lifetime*." Thus the primary condition governing this type of sample is the absence of a person's non-opposition. We thus consider that a deceased person is presumed to consent to a sample, whether for therapeutic or scientific purposes. The person does still have the opportunity to oppose said sample during their lifetime, but this opposition must be expressly stipulated: *"[It] may be expressed by any means, specifically by registration on an automated national registry set up for this purpose*. *It may be revoked at any time.*" (art L. 1232-1 of the French Public Health Code). This opposition may thus be made by any means, which leaves the way clear to many possibilities. However, the preferred mode of opposition is by means of registration on the automated national registry, since this will be routinely consulted before any samples are taken, as a matter of course.

This registration on the registry thus ensures compliance with the wishes of the deceased person, which is thus unequivocal. Article R 1232-6 of the French Public Health Code provides in this respect that "*any adult or minor of at least thirteen years of age may make an entry on the registry to make known their opposition to the removal of their organs from their body after death, either for therapeutic purposes, or to establish the cause of death or for other scientific purposes, or any of these three cases*."

If there is no entry in the registry, or "*if the physician has no direct knowledge of the wishes of the deceased person, then he/she must try to ascertain from loved ones whether the deceased potentially expressed opposition to the donation of organs during their lifetime, by any means, and must notify them of the purpose of the proposed samples*" (Article L. 1232-1, paragraph 3 of the French Public Health Code). The idea here is that even if the physician does not know the deceased person's wishes, and there is no entry in the registry, then he/she is obliged to consult the loved ones to find out whether the deceased had expressed opposition to the removal of samples. However, in this regard, two things are very clear: the physician does not seek the opinion of loved ones, but rather seeks to ascertain the wishes of the deceased person which may have been expressed to the loved ones while the deceased person was alive.

The legislator's intention here was to widen the group of people from whom the deceased's wishes must be collected. The scope was thus broadened to include not only the family (that is to say parents, spouses, and children), but also the deceased person's "loved ones": civil partner, common law partner, and even friends. The aim here was to include those people who were of real importance in the life of the deceased, as well as to restrict attempts made by the family to circumvent the wishes of the deceased, since by asking more people, one is better informed.

The French Public Health Code further states that "*loved ones are informed of their right to know about any samples removed*" and the purpose of said samples (art L1232-2 du CSP).

The rules are not the same in the event that the deceased person is a minor or a person under guardianship, where specific provisions apply (art L. 1232-2 of the French Public Health code).

In fact, the presumption of consent disappears in this case, and written consent is required from either the parental authority or the guardian. As such, each holder of parental authority must necessarily give their consent. The Article does add that if one of the two holders of parental authority cannot be consulted, and only in this case, then the sample may still by taken if the other holder gives their consent in writing. In this case, express consent is essential before a sample can be taken.

It should be noted that an entry in the national registry of opposition can be made from the age of thirteen onwards. As a result, if such an entry exists, then the parents do not have the opportunity to give their consent to the sample, since only the opposition of the minor will be taken into account.

3.3. Conditions of authorization

Even after checks have been made to ensure that no opposition exists, this is not sufficient to remove any samples to be subject to research. In fact, a prior formality is required: "*the Biomedicine Agency must be notified of any samples for therapeutic or scientific purposes, prior to their removal"* (art L. 1232-1 of the French Public Health Code). The Biomedicine Agency is a French national public state agency that came into being following the enactment of the 2004 bioethical law.

Protocols must be sent, prior to their implementation, to the Biomedicine Agency."

The file must contain "*the purpose, title and duration of the research protocols, identification of the declaring party and participants in the protocol along with their titles and positions, the nature of the proposed samples, and the elements that will ensure compliance with the legal and regulatory conditions of the samples.*" The Agency has a period of two months in which to consider the case. During this period, Agency management checks the feasibility of the proposed samples and also monitors compliance with the donor non-opposition procedure. If the file is complete, then the Agency issues an advice of receipt, and simultaneously delivers this to the Minister for Research. It also sends said Minister "*any information it has which may help assess the necessity for the sample or the relevance of the research*".

Two months after the advice issue date, the protocol can then begin unless the Minister for Research opposes a ban, specifically when "*the necessity of the sample or the relevance of the research is not established"* (Article R.1232-18 of the French Public Health Code). In this case, the institution must be allowed to submit its observations. Implementation is of course subject to close monitoring by the Agency and the Minister. At all times, the institution must in fact be able to provide "*the number and nature of the organs removed, the place and date of removal, all documents evidencing non-opposition or consent to the sample, and the progress of research on the organs removed*" (Article R.1232-20 of the French Public Health Code). Finally, the Law states that "*Implementation of the protocol will be suspended or banned if the conditions that justified its authorization are no longer met and after the institution or organization has been invited to submit its observations*" (Article R.1232- 21 of the French Public Health Code). Prior to any decision to suspend or ban, the institution or agency responsible for implementing the protocol is given notice to remedy its failures or else to submit its observations. The suspension period may not exceed one year.

However, these provisions appear difficult to transpose to forensic samples from forensic autopsies.

3.4. Difficulties in applying these rules to forensic samples taken during forensic autopsies

The first issue is that samples taken during forensic autopsies are removed without any checks to ascertain the opposition of the deceased person. By the time the question of scientific research on these samples arises, samples have already been taken. In this context, it is not a matter of determining a person's lack of opposition to a sample, rather the lack of opposition to research on a

previously removed sample. The issue then arises as to whether the absence of consent in the forensic autopsy is final, and is applied to the fate of the samples. There would be no need to seek the person's lack of opposition, and research could then be conducted from the point at which the investigation is completed. Since the deceased did not have the power to ban the autopsy and any samples removed during their lifetime, this would mean that neither is this opposition valid in terms of the possibility of conducting research on these samples.

Turning now to the power of opposition of the family: by law, the family cannot obtain restitution of the samples removed at autopsy, without exception; one might think that since the family cannot decide on what happens to the evidence even when it no longer has the status of sealed evidence – since it is destroyed without the family's authorization – that the family is also unable to oppose the research.

In this case, we consider that the deceased person and their family have lost all powers of decision over these samples. One might consider that once the sealed evidence is no longer in the possession of the court, it becomes the property of the forensic institution which examined it, and that said institution would be able to use the evidence in connection with research if needed, or to order the destruction of the evidence if it considers that said evidence is no longer relevant.

However, although this approach would allow the easy and practical re-use of samples, it seems ethically questionable. The inability to oppose the autopsy is justified, because we are attempting to establish the truth, which renders such inability necessary if the investigation is to be conducted successfully. However, this justification disappears once the investigation is complete, since we are no longer conducting research "in the name of establishing the truth"; thus the opportunity to oppose its use seems to reappear.

A change in the law would thus be desirable, though with some specific amendments in terms of the potential use of forensic samples.

4. A necessary change in the law in France

Today, research on forensic samples from forensic autopsies, though foreseeable, is legally impossible. One of the first reasons for this is that the law provides for their destruction once they are no longer useful to the court. The second reason is that the Biomedicine Agency often states that it is not competent to deliver authorization. The Biomedicine Agency is effectively competent to authorize the removal of a sample to be submitted for research, rather than allowing research on a sample that was previously removed. However, this authorization by the Agency is a prerequisite for research. Currently, no other authority has the ability to grant said authorization. As such, a legislative vacuum exists, since there are indeed samples which could be subject to research, but which, due to a lack of legislation, are not. The third reason is the difficulty, in a forensic context, of seeking the non-opposition of the deceased person in the conditions provided by law.

We consider that the intervention of the legislator is necessary. A proposed Article 230-30-1 could thus be incorporated into the French Public Health Code directly after that concerning the destruction of sealed evidence. In the first paragraph, the Article could provide that "when biological samples taken during a forensic autopsy are no longer necessary to establish the truth, then they may be subject to scientific research."

Such a legislative amendment must also set out the conditions in which research on samples removed from forensic autopsies is possible, specifically the arrangements governing the search to ascertain the wishes of the deceased person.

4.1. Amendments to conditions governing the search for non-opposition of the deceased

One of the two main conditions that must be met in order to conduct research on a sample from a deceased person is that said person does not oppose its removal during their lifetime (Article L. 1232-1 of the French Criminal Procedure Code). The existence of this condition seems to be mandatory even when the sample comes from a forensic autopsy.

How can this opposition be ascertained? First of all, as provided by common law on research, by consulting the French Registry of Opposition, pursuant to which the deceased person is given the opportunity to oppose the removal of a sample, whether for therapeutic or scientific reasons, and thus implicitly to oppose research on a sample performed in connection with an autopsy (Article R.1232-10 of the French Public Health Code).

If the registry does not contain any information in this respect, should the family be consulted, as recommended by the French Public Health Code? (Article L. 1232-1 paragraph 3 of the French Public Health Code).

The ruling by the European Court of Human Rights cited previously sanctioned the fact that samples taken during an autopsy are employed for pharmaceutical use without the family's knowledge.

However, it seems complicated, in a forensic context, to be obliged to consult the family to find out whether the deceased person was opposed to scientific research being conducted on their organs. The announcement of the completion of the autopsy is already a major source of pain for the family, in addition to the unusual circumstances surrounding the death. It seems impossible that the interest of scientific research should be defended in this context. Another solution may be to ask the family at a later date, once the investigation is complete and the samples are earmarked for re-use for research purposes. This solution too seems very difficult to implement. A relatively long period may have elapsed between the death and the end of the judicial investigation; consequently, consulting the families once again could represent an additional, and even unnecessary source of pain.

In this respect, the law must provide an amendment to common law for the specific case of biological sealed evidence. Thought could be given to informing the family, though the family is not obliged to demonstrate the potential opposition of the deceased person. Moreover, said notification is already scheduled by the French Criminal Procedure Code. However, this would be a notification and nothing more.

Article 230-30-1 of the French Criminal Procedure Code previously cited, could be supplemented as follows: "When biological samples taken during a forensic autopsy are no longer necessary to establish the truth, they may be subject to scientific research unless the deceased person expressly opposed this by registration in the French Registry of Opposition. The provisions of Article L. 1232-1 paragraph 3 of the French Public Health Code do not apply in these circumstances."

Logically, once the investigation is complete, the family would be notified of the fate of the samples, namely their destruction or their use for research.

A lack of opposition from the deceased person is not sufficient to ensure that the biological sealed evidence is used in research; an authorization must first be obtained from the Biomedicine Agency.

4.2. The necessary recognition of an authorization from the Biomedicine Agency

As previously discussed, in common law, research on samples removed from a cadaver requires an authorization. "*the Biomedicine*

Agency is notified of any samples for therapeutic or scientific purposes, prior to their removal." (article L. 1232-1 of the French Public Health Code). Thus the removal for scientific purposes is authorized, but not the research itself on a previously removed sample. This distinction is subtle, but it does currently prevent research on biological sealed evidence. As such, it is necessary to include this competency within the scope of action of the Biomedicine Agency. Though it may not schedule major adjustments to the powers of the Biomedicine Agency, this legislative change is nevertheless essential in order to advance the possibilities of research on samples from forensic autopsies.

Article 230-30-1 of the French Criminal Procedure Code previously cited could thus be supplemented by a second paragraph which would provide that: "**the Biomedicine Agency has the power to authorize scientific research on these samples within the scheduled statutory requirements**."

Though the Biomedicine Agency would be given the power to issue an authorization for research on such samples, the terms governing the request for authorization would remain those of common law on research, which seem appropriate to the specific status of samples from forensic autopsies.

This precaution of maintaining a research protocol submitted to the Biomedicine Agency seems essential. In fact, if a sample has already been removed, and the only alternative to research is its destruction, the aim here is to avoid deviations, for instance where a sample is subject to research but the appropriate conditions have not been met and verified. Such deviations may exist due to the very removal of the sample. The authorization given by the Biomedicine Agency strikes a balance between progress in science, and respect for the interests of the deceased person.

5. Conclusion

Research on forensic samples from forensic autopsies is thus currently legally impossible in France. In fact, at the moment, all samples are destroyed after the judicial investigation. However, the legislator did not foresee all possibilities, such as scientific research. Nevertheless, 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 to common law relating to medical research on samples removed from cadavers. Even so, for this to be possible, a legislative change seems necessary, primarily to expressly authorize this research, to adapt research into the potential opposition of the deceased person and to strengthen the jurisdiction of the Biomedicine Agency. This possibility would be a true breakthrough, as it would be of genuine use from a scientific viewpoint. Today, nothing seems to stand in its way except a simple legal obstacle.

Besides scientific research, are there are any other options to consider? We could move on to scientific collections. Rather than simply being destroyed and vanishing without being of any real use, could these samples instead be included in collections of biological samples? Obviously, the establishment of collections is subject to authorizations, specifically those of the Minister for Research, and the Regional Health Agency. The establishment of such a collection is undertaken for scientific purposes (excluding care and diagnosis), and for the specific research requirements of a given institution.

It is essential that research in forensics is able to develop in a calm, legal manner.

This problem exist in others countries. It would be interesting to harmonize the legislation about this subject. But, in order to do this harmonization, it is necessary to know the legislation and the difficulties in each country.

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References

1. Martrille L, Duguet AM, Zérilli A, Saliéro G, Baccino E. Establishment of collections in anthropology: scientific interest and ethical aspects. *J Med Leg* 2004;**47**:31–7.
2. European Court of Human Rights. Judgment of January 13, 2015. Elbert-Latvia-612438.
3. Kurosu M, Makai T, Ohno Y. Regulations and guidelines on handling human materials obtained from medico-legal autopsy for use in research. *Leg Med* 2003;**5**:S 76–S78.
4. Bernice S, Hofner MC, Mangin P. Research involving biological material from forensic autopsies: legal and ethical issues. *Pathobiology* 2009;**76**:1–10.
5. Bennet JR. The organ retention furore: the need for consent. *Clin Med* 2001;**1**:167–71.
6. Giannoukas A, Micyhalodimitrakis E. Consent for organ and tissue retention in British law in the light of the human tissues act. *Med Law* 2006;**25**:427–34.
7. Ito T, Nobutomo K, Fujimiya T, Yoshida K. Importance of explanation before and after forensic autopsy to the bereaved family: lessons from a questionnaire study. *J Med Ethics* 2010;**36**:103–5.
8. Court of Appeal of Toulouse, April 28, 2009. Comment by A. Chioccarello The lack of status of human samples reveals the powerlessness of law in the use of elements and products of the human body. *Gazette du Palais* 2010;**16**:40.
9. Law No. 2011-525 of May 17, 2011, on simplifying and improving the quality of law.
10. Law No. 2004-800 of August 6, 2004 [on bioethics].