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Forensic autopsy. The particularities of consent for research

Sorin Hostiuc

Carol Davila University of Medicine and Pharmacy, soraer@gmail.com

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I. Introduction

I.1. Clinical versus forensic autopsy

Forensic autopsy has as its main goal to find out the truth about the causes and circumstances of death, when there is a reasonable suspicion to be caused by a violent act(DiMaio & DiMaio, 2001; Dolinak, Matshes, & Lew, 2005; Fatteh, 1973; Saukko & Knight, 2004). These circumstances vary from country to country but generally include deaths caused, with a certain degree of probability by a traumatic event (mechanical asphyxia, accidents, falling, drug overdose or other intoxications, explosions, burns) or deaths occurring in an unexpected way (sudden death, the death of persons whose health status was monitored periodically, and so on)(Dermengiu, 2002). Main differences between forensic and clinical autopsy are the ones regarding the person who is authorizing it and how it's done. Forensic autopsy is performed at the request of a state official (police, prosecutor, judge), is mandatory, regardless of the wishes or demands of the legal guardian, and is, in most legislatures, complete; clinical autopsy is performed only if the legal guardian accepts it and may not be complete - if a certain cause of death is identified the autopsy can be stopped(Dermengiu, 2002).

As the legal guardian cannot refuse a forensic autopsy, the forensic physician is free to perform any procedures considered to be necessary for finding out the truth (in order to answer to the objectives asked by the authority). The required procedures are of two basic types (1) procedures and techniques common to any forensic autopsy, and (2) specialized procedures, needed to answer specific objectives. Both may include removal of tissues, body fluids, the use of various laboratory techniques like histopathology, histochemistry, immunohistochemistry, micro dissections, toxicological analysis, tanatochemistry, serology, genetic, anthropology or entomology(Knight & Saukko, 2004). This wide spectrum of analyses may lead to the identification of morphological, pathological, histological,

microbiological, physiopathological or genetic data, which may have significant consequences for healthcare. This makes forensic investigations to have an increasing importance, especially since the number of clinical autopsies has decreased over the last years, and animal experiments give results that are not always reproducible on humans. However forensic research on the deceased is not specifically required by authorities requiring the forensic autopsy, as it's not a part of the information needed for finding out the truth regarding the circumstances of death. Moreover, in most countries there is no explicit law on how biological materials obtained during a forensic autopsy can be used for research purposes.

II. Autonomy versus respect for the dead

II.1. Autonomy of the deceased

Even if we cannot speak stricto sensu about autonomy in deceased subjects, there are three rules that can replace, in specific situations, this principle in the analysis and validation of consent: the wishes of patient expressed before his death, authorization by proxy (legal guardians) and authorization by authority.

Ways to express the autonomy for actions regarding one's body after death.

A person may express his/her wishes regarding the postmortem related issues before death, and thus exercise his/her autonomy in one various ways, from signing an informed consent to extrapolation, knowing the subject's cultural, social and religious perceptions

Authorization by proxy

Regarding the authorization by proxy we consider that it can be taken into consideration in two major instances:

- when the decision is in line with the views and beliefs of the subject (and is fulfilled the presumption of autonomy). Proxy authorization cannot be allowed if it is not in accordance with the opinions or beliefs of the deceased person. This is why some laws suggest the need of a two-part consent in the cases in which removal of postmortem tissues is needed for research purposes. The first layer is represented by taking reasonable measures to determine whether the deceased was not against sampling (e.g. for religious reasons) and the second part is the actual authorization by proxy(Medical Research Council: Human tissue and biological samples for use in research: operational and ethical guidelines., 2001).
- when the decision is made based on the principle of beneficence – the purpose of the tissue sampling procedure can lead to a possible (research, education) or certain greater good (transplant, studies of intubation) to others. This situation must be allowed only if three conditions are met: (1) is not against previously expressed wishes (2) is not against the known/supposed opinions / beliefs of the deceased and (3) does not directly give a material advantage to the proxy (leading to a conflict of interest). When the decision creates a real or potential benefit for proxy occurs a conflict of interest that cancels the validity of the authorization by proxy (a person's biological materials can be disposed of for financial benefits(European_Parliament, 2010)).

II.2. Alteration of the voluntarianism of the legal guardians

Some authors have described the presence of a pressure, generated by the judicial character of the forensic autopsy, which could theoretically alter the voluntarianism of the legal guardians that, in extreme cases, could potentially void the validity of the authorization obtained for research purposes(Elger, Hofner, & Mangin, 2009). Preventing this potential problem can be done by explicitly informing the legal guardian that accepting to include the case in a research has no effect on the conclusions of the autopsy report and / or by taking the consent after a

period of time once the autopsy has been conducted (as long as this option exists for that specific research).

II.3. Authorization by authority

Authorization by authority is the element that distinguishes forensic autopsies from most other medical acts (including clinical autopsies) and is defined as a medical act authorized by a state authority(S. Hostiuc, 2014). This authorization by authority may be in turn with or without respecting the subject's voluntary decision. In authorization by authority, respecting the voluntary decision, the subject may refuse a medical act, but this refuse may have civil or penal consequences. A classic example is blood sampling in order to determine the alcohol level to drivers. They have a legal obligation to accept blood sampling when there is a reasonable suspicion that they are drunk. They can refuse the sampling, but this may lead to legal consequences (often an increase in jail time compared to the case in which is found drunk but accepts the sampling). In authorization by authority without respecting the voluntary decision of the subject, he/she doesn't have the right (or cannot) refuse a medical procedure. This is the situation we are in when an autopsy is deemed mandatory by an authority - when the autopsy is decided by a state authority it can't be refused by either the legal guardian(s) or previous decisions of the deceased. The authorization by authority strictly allows the procedures needed in order to respond to the objectives. Any additional maneuvers or a higher invasiveness than the minimum necessary to meet the conditions mentioned above are not a constituent part of the authorization by authority and when necessary (including educational or research activities purposes), it requires an additional agreement from either the deceased or legal guardians, as presented above(S. Hostiuc, 2014).

II.4. Respect for the dead.

Respect for the dead is a component of piety (besides treating with consideration the bereaved families), is one of the basic moral principles in postmortem ethics(Preu, 2011) and is derived from the duty of respecting the dignity of the deceased. For an extensive discussion on this duty see the study conducted by Burns(Burns, 2007). This concept partially overlaps another two:

- the principle of non-maleficence; overlapping is present when comparing the mode of action - minimizing the actions leading to a to supplementary moral or material (biological) prejudice, and is absent when compared to the purpose (as non-maleficence can not be defined in relation to a non-person).
- respect for the embryo; the overlap is absolute in relation to the mode of action - minimizing the actions leading to supplemental moral or material (biological) damage, and partial in relation to the purpose - respect for the embryo is defined in relation to a potentiality of a human being, that can become a human being (after birth) or not (abortion, miscarriage). If it becomes a being, the principle of respect for the embryo turns into non-maleficence (and the moment is usually associated in bioethics with the moment of childbirth) and if not, it becomes respect for the deceased(Sorin Hostiuc, 2014; Warren, 1997).

III. Consent

III.1. Under what conditions can posthumous tissue be used for research?

In clinical practice, the informed consent is targeted, meaning that it is obtained in relation to a specific medical intervention - the patient is informed about the disease, potential interventions with risks, benefits and possible complications then takes a decision that once approved and validated by signing a consent form, authorizes the physician to perform a specific procedure (diagnostic or therapeutic, for medical or research purposes). The

procedure can be performed only if there is a medical indication and if there are potential benefits that the patient considers to be more important compared to potential negative effects. In deceased persons, the content of the consent for obtaining biological samples for research purposes is quite different, because the information is primarily directly towards informing the legal guardian about the necessity, methodology, and purpose of the sampling (and which may or may not have a secondary diagnostic purpose). Consent is not focused anymore on realizing a medical intervention but upon (1) authorizing the study as it is presented by the researcher and (2) the future uses of the biological samples.

Types of posthumous consent

Due to this shift we often discuss in postmortem investigation about two types of consent - a ***general*** one, whose purpose is to authorize biological sampling, and a ***specific***, targeted one whose aim is to authorize a specific use of the sampled products.

III.2. Secondary use of the sampled products

Biological products sampled from a deceased for research or those stored in bio banks may theoretically be used later in another study. Authorization by legal guardians (or the patient) should also refer to this situation. And there are more possibilities:

- Opt-in - patients/legal guardians must accept the use of the biological samples for secondary purposes in order to validate the consent. It's a method that provides the fewest ethical issues because in this case they can be properly informed about this possibility, and can take a fully informed decision.
- Opt-out - patients / legal guardians mustn't refuse the use of biological samples for secondary purposes in order to validate the consent(Vellinga, Cormican, Hanahoe, Bennett, & Murphy, 2011). In this type of informed consent form, the subject/proxy must check the options with which he does not agree, while in the opt-in type, he must check all the options with which he agrees. In the opt-out system, everything that is left unchecked is considered to be approved

by the subject/proxy. The method is often used in general consent, because in this the investigator does not specifically inform the person who authorizes about the exact procedures / maneuvers which will be done in that selected case.

- Presumed - products collected during a forensic autopsy can be used later for educational or research purposes as long as family members do not object. For this to be allowed it must be clearly stated in the national legislation and the method is usually only allowed in particular instances. For example, the Swiss legislation allows the use of minimum quantities (whose sampling does not generate additional harm to corpse) without the need of an informed consent under the following conditions: products are anonymous, the amount is minimal (any part of organ or the entire organ is considered not to be a minimum quantity) and there are no documents proving that the deceased would have refused the procedure(Elger & Caplan, 2006).

III.3. When do we take the consent ?

If the clinical medicine informed consent can only be taken before diagnostic, therapeutic or research procedures (because one of the purposes of the authorization is to allow the initiation of a medical intervention) in forensic research things are more complicated because the one who authorizes the initiation of the autopsy is not the same who is entitled to allow the use of biological products for research. Therefore, the authorization for sampling biological products can be taken before, during or after the autopsy. The authorization for sampling before the initiation of the autopsy is needed when the study is clearly defined (in this case the consent is recommended to be targeted). The authorization during autopsy is taken when the forensic physician identifies, during the autopsy, some specific elements which makes him want to include the case in a research and will require additional sampling of biological tissue (besides the biological tissue taken strictly for forensic purposes). The forensic physician will

not be able to sample additional bodily material without the consent of legal guardians, which is mandatory to be obtained before closing the body. The authorization after the autopsy may be taken for studies that do not need additional biological samples to the ones specifically collected for forensic purposes. Therefore, those tissues would have been sampled anyway and the legal guardians consent is not necessary for sampling, but only for use in research. In clinical autopsy the authorization must always be taken before the start of the autopsy because it is needed for approval of the procedure. A supplemental authorization from the legal guardians is needed if the case is to be included in a study.

III.4. Elements of posthumous consent

When preparing the consent form, needed for biological sampling in forensic autopsies the following elements should be clearly recognizable in the form (a-d) and for each of the elements presented in paragraphs numbered 1 to 9, the legal guardian should be able to refuse them individually or select from two or more options:

a. The legal guardian has read the information detailed in the form, which is in accordance with the oral information, made by the doctor, and that he understood it.
b. Donor's personal data will be kept in secret from third parties (with the exceptions clearly stipulated by law). The confidentiality refers only to the information used for or obtained during the research. Personal data or results obtained during the autopsy are not secret from the authority that has authorized the forensic autopsy.
c. the legal guardian or other relatives will not obtain financial benefit from the research
d. general information about study, sampled tissue, methods, and expected results. The first two elements must be disclosed both in a general consent and targeted. The last two items are required to be submitted in a targeted consent and are optional in a general consent.

1. Consent for sampling. It may be simple (Yes/No), in case of a generic consent, but it is recommended to include details regarding the types of biological products and their quantity. It is necessary only if biological samples are obtained in excess to those collected in order to meet the objectives of the expertise.
2. Consent for storage. The legal guardian should be able to agree with the storage of biological samples as well as the period of storage (until the case is closed, until the end of the research, a certain number of years after the end of the research, indefinitely). This paragraph must be included if (1) is sampled more biological material than needed for the purposes of the forensic autopsy or (2) for storing an additional time biological samples obtained for the purposes of the autopsy.
3. Information on the way the biological samples are removed after the storage period, previously agreed upon, has ended as well the selected method for removal.
4. Consent for linking biological samples with clinical data. Collected biological samples can be irreversibly anonymized, reversibly anonymized or can remain non-anonymous. In most studies in the field of forensic medicine personal data or other data obtained during the autopsy are needed in the study (age, sex, height, associated pathologies, morphometrical aspects, and so on), making anonymization rather an exception than a rule for the researcher.
5. Consent for the use of photographic or audio-video materials and the description of the way the researched hides identifying information from these. In most cases all identification data must be hidden (face, particular signs, tattoos, earrings, etc.). If one or more identification elements are essential to be presented in a scientific paper this should be brought to the attention of the legal guardians, who should give a specific consent for this. Also all non-essential elements of identification must be hidden.
6. Consent for a follow-up contact of the legal guardians and the preferred method of contact. It may be necessary to obtain additional data or, on the contrary to inform them about issues,

identified during the research, which may have significant impact on their relatives. These information may however not be shared with the relatives until the official investigation is over (except for cases in which a immediate danger is suspected). If the researchers identify such a case they can inform the legal guardian or other interested parties, but only with a prior agreement from the authority who authorized the forensic autopsy.

7. Consent for reusing biological samples. Some biological samples can be reused in other research studies, and the family members must to agree with it in order for this to be permitted (except for studies deriving from the initial one).
8. Consent for disclose to third parties. Some tests may be performed in third party laboratories. In order to transfer biological samples from the initial sampling and processing unit is needed a specific consent given by legal guardians. Normally the biological samples are to be transferred anonymous linked in order to prevent any risks of breaching the confidentiality.
9. Consent genetic testing. Because the genetic material is partially common with other family members it is recommended the consent for these genetic tests to be obtained specifically, especially if potentially sensitive aspects (like racial data) are studied(S. Hostiuc, 2014).

IV. Consent issues depending on type of cadaver materials

Forensic studies can be made on the entire body, on biological samples collected from the deceased, archived material or necropsy reports. Biological products collected from the deceased can be collected in order to answer to the objectives required asked by the authorising authority, or collected specifically for research purposes, and the amount may vary from a few milligrams of biological tissue or fluid up to whole organs. Every situation has specific ethical issues that we will try to summarize in the following pages.

IV.1. Experimentation on whole body cadavers

IV.1. a. Experimentation having as a consequence the mutilation of the cadaver,

Experimentation having as a consequence the mutilation of the cadaver, defined as significant alteration of the normal appearance, which cannot to be substantially recovered using thanatopraxy techniques. Normally they should be forbidden with some minor exceptions, only if there is an explicit consent for it, and the following three conditions are met: (1) the resulting beneficence is significant, (2) there are no alternative ways to obtain the same results, and (3) all necessary actions will be taken in order to respect the deceased(Burns, 2007). These experiments cannot be conducted by relying on the authorization by authority because (1) they are not the within the purposes of a forensic autopsy and (2) because invasiveness is higher than the minimum necessary to meet the objectives or respect the methodological steps of the forensic autopsy.

IV.1.b. Whole body experimentation without mutilation.

Here the classical example is the use of deceased persons by physicians who want to learn a particular surgical or medical-surgical technique (how to properly intubate a person, how to perform different invasive methods, or surgery) that could not be learned otherwise than with high-risks on living patients(Baskett & Steen, 1999). Performing these procedures on corpses leads to immediate benefits for other patients who can be saved by learning these invasive procedures. However the approach is clearly utilitarian and contrary to the Kantian principle of finality. Therefore we consider that there is no valid ethical argument to allow these interventions, even though there are plenty of studies showing that some doctors consider it permissible from a bioethical point of view(Cook, 1998; Garnes, Vassbo, & Forde, 1999; Hayes, 1994; Morhaim & Heller, 1991; "Teaching intubation skills using newly deceased infants," 1991)

IV.2. Forensic studies on biological samples.

Biological samples obtained from the deceased can be taken in order answer the objectives of the forensic autopsy, in which case the research is complementary to the autopsy, or supplemental materials are specifically taken for research purposes. When the biological samples are taken primarily for forensic purposes they can be used for research either by using the same techniques used for forensic purposes or by using supplemental techniques and procedures, conducted on the extra or residual sampled material.

IV.2.a. Supplemental sampling of biological products

Supplemental sampling of biological products should only be permitted when a targeted consent is obtained because in this case the sampling should be based on a known, well established research protocol and the researcher knows exactly what procedures are required. If further procedures are needed, in order to answer the objectives of the research as detailed to the legal guardian, they can be performed upon the biological samples already collected, without the need for an additional consent, if they are similar in either technique or purpose. For example, if the initial research protocol states the use of a specific antibody for identifying apoptosis and in a later stage the researcher(s) identify another, better antibody for apoptosis, a new consent is not needed if the staining is conducted upon the same tissue for which a consent for a study of apoptosis was obtained("Recommendation Rec(2006)4 of the Committee of Ministers to member states on research on biological materials of human origin ", 2006). The possibility of using new techniques or protocols should however be clearly stated in the targeted informed consent if such procedures are considered probable by the researchers before the consent is obtained. In this case the consent should contain information about the experimental procedures required to be performed, the objective of the study, their potential positive effects for the family (e.g. identification of genetic abnormalities that can be

further identified in other family members) or for the society, secondary uses (the formulation should be of the opt-in type) and limits (in terms of storage, reuse, etc.)

IV.2.b. Supplemental methods and techniques on biological products sampled for the purpose of the forensic autopsy

Supplemental methods and techniques on biological products sampled for the purpose of the forensic autopsy may be used for research purposes when either a generic or a targeted consent is obtained depending on the particularities of the study. If a generic consent is preferred, and if the study is not clearly defined (or the case is selected for a case report), an opt-out technique may be used

IV.2.c. Using the results of the forensic autopsy for research purposes

Using the results of the forensic autopsy for research purposes can be accepted after the signing of generic opt-out consent, with the observation that conditions 1, 2, 3, 6, 8 are not always needed (especially if the study ends before or with the completion of the autopsy report).

IV.3. Stored biological materials.

They can be used only if there is a prior consent that allows their use or if a specific consent is obtained from the legal guardians.

IV.4. The paraffin blocks or other processed biological samples.

As long as there was a prior signed consent for its use in research purposes, additional tests should be allowed because the type of procedure is not changed, but only technique or an element of the technique (another stain, another antibody, etc.). The initial consent should however state the permission for further uses of the processed samples. Additionally there are studies showing that once a legal guardian has given its consent for the use of biological samples collected for a specific a study they will allow, with high probability the reuse in similar studies(Elliot et al., 2008).

IV.5. Data obtained during forensic autopsy for retrospective studies.

Some national or international regulations allow using data obtained from forensic autopsies to be used in retrospective/archival studies, without the need to obtain an explicit consent("Ordin pentru aprobarea Normelor procedurale privind efectuarea expertizelor, a constatarilor si a altor lucrari medico-legale nr. 1.134/ C/25 05.2000 al Ministerului Justitiei si nr 255/ 04.04.2000 al Ministerului Sanatatii si Familiei (publicat i□n Monitorul Oficial, Partea I, nr.459/19.09.2000)," 2000). In these situations we recommend, when possible the use of a generic form of consent at least where identifying data is presented or when a specific case is selected for a report.(Sorin Hostiuc, 2014).

V. Examples

Case 1. A researcher wants to use whole body cadavers to study the biomechanics of falls from various heights. According to the principles presented above, such a study cannot be accepted by an Ethics Review Board as (1) the resulting beneficence is minor, represented by a better knowledge of the biomechanics in falls, that may or may not aid in some cases the differential diagnosis between a simple fall and a projected fall; (2) there are alternative methods to obtain that benefit (e.g. using molds), and (3) the pietat principle is not respected.

Case 2. A researcher wants to use paraffin embedded blocks of various organs sampled during the autopsy for a study of sudden cardiac death (more than 400 blocks). The samples were taken over the course of 20 years, and the sampling was performed for forensic purposes. A consent for research purposes was obtained. In this case the Ethics Review Board could approve the study, as long as in the initial consent form was specified the possibility for additional research using the stored block or whether the study protocol is similar to the one for which the consent was obtained.

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