

Guidance for pathologists conducting post-mortem examinations on individuals with implanted electronic medical devices

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Context

This document provides supplementary guidance to the College's guidelines on the Coronial autopsies, *Standards for Coroners' pathologists in post-mortem examinations of deaths that appear not to be suspicious*

(www.rcpath.org/Resources/RCPATH/Migrated%20Resources/Documents/G/G136_CoronersPMsPerfStands_Feb14.pdf).

This document aims to provide advice to pathologists conducting standard Coroners' post-mortem examinations. It also provides advice to those conducting consented post-mortem examinations.

This document should not be regarded as legal advice. If necessary, formal legal advice should be obtained as necessary from relevant legal service providers.

The circumstances of each case will vary and it is recognised that the pathologist conducting the case will use their own clinical judgment to assess the need to obtain any further specialist investigation or opinion and to come to a conclusion as to the cause of death based on the information available to them and on the balance of probability.

The needs of other circumstances, such as mass disasters and special post mortems, are not specifically addressed in this document although its contents may be of use in these situations. Particular attention is drawn to the areas in this document relating to safety which remain relevant to any type of post mortem.

Implanted electronic medical devices are increasingly used in the management of patients. When a post-mortem examination is performed, a pathologist conducting the examination should consider the possibility that such devices, when present, may have played a part in the death.

Electronic medical devices (EMDs) with downloadable time- and date-correlated memory functions include implantable cardiac pacemakers and defibrillators, drug pumps, insulin pumps, blood glucose monitors,¹ peripheral nerve stimulators,² implantable loop recorders³ and implantable neurostimulation devices.⁴

While many individuals with an implanted EMD will have died from a cause unrelated to the presence of the device, consideration should be given to retention and interrogation of any device as part of a post-mortem examination where, based on the clinical judgement of the pathologist conducting the post mortem, such studies are likely to contribute to establishing the cause of death. The necessity for such retention and interrogation of any device will in part depend on the type of post mortem being conducted and on the burden of proof required in the case. Bearing in mind that the burden of proof for Coronial post mortems is the "balance of probability", it may well be unnecessary to conduct such studies in Coronial cases when an adequate cause of death is found; however, in other situations, e.g. consented post mortems, such retention and interrogation of any implanted device may be desirable whatever the cause of death appears to be at post mortem. However, retention and interrogation of any device as part of a post-mortem examination is likely to be particularly important in cases where no macroscopic cause of death is apparent, as some devices are associated with adverse events, thus may have contributed to or caused death.

Implantable devices may have specific identifying data on or associated with them. This may be of particular use in identifying an individual; however it should be remembered that in some parts of the world such devices may be reused, which may have implications in identifying the deceased.

Ownership of implantable devices

It would seem reasonable to consider any implantable medical device as the personal property of the individual in whom the device resided, unless other specific circumstances apply (e.g. in the case of research implants, etc). Consequently, after the post-mortem assessment (including any

interrogation, etc.) is complete, executors and administrators should be asked whether they wish to be given the device for distribution as part of the estate, whether EMDs should be disposed of or whether the EMDs may be permanently retained or reused. This information should be obtained in writing.

Further information regarding ownership of such implantable devices, including an example of a form relating to their post-mortem usage, can be found in Appendix A.

The role of the autopsy

When dealing with the post-mortem examination of an individual who has an EMD present, a number of possibilities should be considered:

- the cause of death is due to a disease process, for which the EMD has neither caused nor contributed to death, for example an individual who died as a result of a ruptured aneurysm who has a cardiac pacemaker
- the death is directly due to the presence of the implanted medical device, for example an individual who develops sepsis following insertion of a cardiac defibrillator device
- the death is due to a malfunction of an implanted medical device.

Pathologist advice to legal authorities

When a post-mortem examination is performed on behalf of a legal authority, for example a Coroner, and the pathologist conducting that post mortem believes, based on their clinical judgment of the case, that an implanted EMD may have played a role in the cause of death or be relevant to it, the authority should be advised of the benefit of retaining any implanted EMD for the purposes of further examination. This advice should be noted in the post-mortem report.

If the post mortem at which the implantable device is identified is conducted under the auspices of the Coroner, the need for the device to be interrogated should be discussed with that Coroner or their officer, and the responsibility for arranging that interrogation should lie with that Coroner and be facilitated by their officers in a similar way to toxicology and other similar investigations. While the pathologist should provide advice and assistance where needed to the Coroner or their officers to facilitate this process, the College does not believe that the onus is on the pathologist to arrange the interrogation of any device.

If the post mortem at which the implantable device is identified is conducted as a consented post mortem, the pathologist (or mortuary staff) should liaise with the team responsible for that implantable device to arrange for its interrogation. However, if they are unable to help, it may be necessary to contact the manufacturers directly. The most practical way to arrange interrogation of any device will depend on the specific circumstances of each case and on the clinical judgment of the pathologist performing the post mortem.

Any report arising from such an interrogation should ideally be written in an understandable way that can be incorporated into a post-mortem report or other report if necessary, in a similar way to toxicology reports. Such reports are best produced by experts in such devices.

Risk assessment for the examination

Attention has been drawn to hazards to the pathologist and other mortuary staff when dealing with implantable defibrillator devices,^{5,6} which may deliver a shock to those who come into contact with them if not deactivated prior to a post mortem. It is therefore essential to ensure that any such device is fully deactivated before a post mortem is started.

In a similar way, care should be taken to ensure no implantable device of any type poses any form of risk to those conducting a post mortem or handling the body. The team responsible for the implantable device or the manufacturers may need to be consulted to allow a thorough risk assessment to occur in such cases and to facilitate full deactivation of the device.

If there is any history of an implantable device within the deceased, the exact nature of that device should be ascertained prior to the post mortem commencing. This should include the method of deactivating the device if this is necessary to allow a post mortem to be conducted safely. If the post mortem is to be conducted under the auspices of the Coroner, it is the responsibility of the Coroner or their officer to obtain that relevant information, to the satisfaction of the pathologist (in a similar way to obtaining other aspects of the relevant history). If the post mortem is to be a consented post mortem, it is the responsibility of the clinical team requesting the post mortem to provide relevant information about any device. No post mortem should be conducted unless the mortuary staff and pathologist are satisfied that any implantable device present does not pose any danger to those conducting the post mortem or handling the body.

If a device is only identified at post mortem, the post mortem should be stopped until the exact nature of that device is ascertained and deactivated if necessary. The team responsible for the implantable device or the manufacturers may need to be consulted to provide the relevant information as to the nature of the implantable device and how it can be deactivated. The responsibility for ensuring this occurs lies with the Coroner (or their officer) or with the clinical team requesting the post mortem, depending on the nature of the autopsy being conducted.

Further advice on how this can be facilitated, and on the dangers of certain devices, is available from the Medicines and Healthcare Products Regulatory Agency (Medical Device Alert MDA/2008/068).⁷

Cardiac pacemakers

When dealing with the investigation of a patient with a cardiac pacemaker which, based on their clinical judgement of the case, the pathologist conducting the post mortem believes may have contributed to the cause of death, arrangements should be made for a cardiac services department to interrogate the pacemaker, and information regarding the terminal events to be obtained. When this is not possible, it is advisable to consider retaining the device and arranging for the terminal rhythm to be determined by the manufacturer if no obvious cause of death is found. This may, in certain circumstances, provide useful electrophysiological information regarding any terminal arrhythmia that may have occurred. Such retention and investigations should be organised by the Coroner if the case is under their jurisdiction, or by the other relevant controlling body in other cases, but should be discussed with the pathologist conducting the case.

Even in cases where the presence of a device cannot be linked to the death, interrogation of the device can give useful information to the investigating authorities. For example, a highly accurate time of death can be given⁸ and information regarding the preterminal rhythm of an individual's heart prior to a road traffic collision can be obtained.⁹

Some implantable defibrillators have been recalled by manufacturers as their use has been linked to deaths,¹⁰ and the pathologist may be the first person to recognise such an adverse event.

The possibility of cardiovascular implantable electronic device-related infective endocarditis (CIED-IE) should be considered and the examination conducted in such a way that samples are taken for microbiological examination where indicated.¹¹

As part of documenting the post-mortem examination, the location of any device should be described in the report and a statement made regarding whether or not it was felt that the device may have contributed to the death. The results of any interrogation of the device should be documented in the report and interpreted alongside other information used in arriving at a

suggested cause of death, in a similar way to the use of toxicology reports. The fact that the device has been removed from the body should be documented in the report.

Insulin pumps

Implantable insulin pump systems are generally regarded as an effective treatment for individuals with poorly controlled diabetes, and the risk of hypoglycaemia and ketoacidosis is not thought to be increased in these patients.¹² However, adverse events have been commonly reported in patients using these devices, with one study finding adverse events occurring in 11.1% of patients over a 16-week study period.¹³ The fact that adverse events may be associated with these devices should be considered by pathologists investigating deaths, and consideration should be given to retaining the device and subjecting it to appropriate analysis where deemed necessary in the clinical judgement of the pathologist conducting the post mortem. A review of safety issues in such devices discusses potential areas of concern.¹⁴

General considerations

Some implantable defibrillators have been recalled by manufacturers as their use has been linked to deaths,¹⁰ and with this in mind it is important to consider that the pathologist may be the first person to recognise an adverse event related to any implantable medical device.

The possibility of CIED-IE or infection related to any implantable medical device should be considered where relevant. When, in the clinical judgement of the pathologist conducting the post mortem, such an infective process is a possibility, the examination should be conducted in such a way that samples can be taken for microbiological and other relevant examination where indicated.¹¹

Removal of any implantable device should be conducted under the guidance of the pathologist performing the autopsy. Care must be taken when any such device is removed to reduce the risk of artifactual damage to the device or its leads. Both the device itself and its leads should be examined to exclude the possibility of damage to them being responsible for any device malfunction.

As part of documenting the post-mortem examination, the location of any device should be described in the report and a statement made as to whether or not it was felt that the device may have contributed to the death. If available at the time of writing the report, the results (or a summary of them) obtained by any interrogation of the device should be documented in the report and if possible interpreted alongside other information used in arriving at a suggested cause of death. It is, however, recognised that in complex cases, especially those conducted for the Coroner or other similar authorities, such information and interpretation may be extremely delayed and may depend on other information from multiple sources not available to the pathologist conducting the post mortem at the time they write their report. In such cases, this should be stated in the post-mortem report and if necessary reflected in any suggested cause of death provided. The fact that the device has been removed from the body should be documented in the report.

Reporting adverse incidents to MHRA

If an adverse incident is suspected or proved, a report should be completed and sent to the Medicines and Healthcare Products Regulatory Agency (MHRA).¹⁵ The responsibility for doing this lies with the Coroner if the case is being conducted under their jurisdiction, or by the team responsible for the implantable device if the procedure is conducted as a consented post mortem. The pathologist conducting the case should highlight the need for such a report to whichever of these is responsible.

Further information relating to adverse event reporting is also available in the MHRA's Directives *Bulletin no. 3 Guidance on the operation of the EU vigilance system in the UK*.¹⁶

Specimen cause of death statements

- 1a. Hypoglycaemic coma
 - 1b. Malfunctioning insulin pump inserted for type 1 diabetes mellitus.
-
- 1a. *Staphylococcus aureus* bacteraemia
 - 1b. Abscess around pacemaker inserted for bradycardia
 - 2. Diabetes mellitus (Type 1).

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Appendix 1 Legal advice to the College concerning post-mortem examinations involving implanted electronic medical devices

1. I am instructed to advise The Royal College of Pathologists in relation to Guidance the College intends to issue, concerning various matters arising from post-mortem examinations where the deceased person has an implanted electronic medical device (EMD). I have had sight of the October 2014 draft Guidance, which does not address the topics on which I have been instructed to advise, but sets out advice on other areas of concern to pathologists conducting such examinations. I understand that the publication is aimed at providing guidelines, but is not to be treated as legal advice to pathologists.

Who is the legal owner of an EMD extracted at post-mortem?

2. To answer this question, it is first necessary to ascertain whether an EMD would be treated as akin to human tissue, or as a chattel (personal property, distinct from land). There is no authority yet on the question of whether as a matter of law, an EMD is to be treated as a chattel or as part of the human body, but I think there are very good reasons to consider that an EMD would be treated as personal property:
3. First and most obviously, EMDs are not made of human tissue (to my understanding). When inside the body, EMDs are not converted into different substances in the way that, for instance, dissolvable stitches are.
4. Before implantation, EMDs are clearly personal property, most likely owned by the Trust or equivalent body operating the hospital where the procedure took place to implant them. EMDs' designs are patentable. Parts of the human body cannot be patented, as European Community patent law makes clear: "*The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions*" (Directive 98/44EC Article 5(1), although Article 5(2) does permit patenting of elements isolated from the human body or derived by means of a technical process).
5. Consequently, at the point of implantation, property passes from the Trust (or equivalent) to the patient receiving the EMD. Again, there is no clear authority for this being the case, but there appear to me to be compelling arguments in favour of this analysis:
6. I am unaware of any Trust or similar body, in the NHS or private practice, notifying recipients of EMDs of who owns them following implantation. The obvious implication to draw therefore from the facts is that **property passes to the recipient**. The recipient is free to take away the device inside their body and retain it indefinitely. The Trust (or equivalent) never asks for it to be returned.
7. The consequence of this analysis is that, **on death, the property right in an EMD passes to the deceased's estate**, in the same way as clothing or jewellery on the deceased at post-mortem would pass to the estate.

What should be done with an EMD retained and interrogated in a post-mortem? Does it make a difference if the post-mortem is performed on a Coroner's request or at the request of the family or hospital?

8. Once the analysis of the EMD for the purposes of the post-mortem is over, just as with other property found on or in the body of the deceased, given that it is property of the estate from the time of death, a pathologist cannot act in relation to it as though it were his or her property. **The property right vests in** (i.e. temporarily belongs to subject to strict legal

duties) **an executor** where there is a will from the time of death, **and similarly, in an administrator** where there is no will, from the time when there is a grant of administration.¹

9. The executor (where there is a will) or administrator (where the deceased died intestate) is responsible for sharing out the property in the estate.
10. Consequently, where pathologists have possession of EMDs after analysis, **executors and administrators should be asked whether they wish to be given the EMDs** for distribution as part of the estate, **whether EMDs should be disposed of or whether the EMDs may be permanently retained or reused (in other words, and I would advise expressly stating in writing, that property will pass to the legal entities for which the pathologists are working, for instance Foundation Trusts or Health Boards)**. I have drafted a sample set of written questions annexed to this Advice.
11. Sometimes there will be neither an executor nor an administrator, for instance where there is no will, and the surviving spouse jointly owned all property prior to the death, so owns it outright after the death. In this circumstance, **the beneficiary of the estate** (i.e. the person who owns it following the death) **is the appropriate person to be approached** about what should be done with the EMD. For convenience I refer only to the executor or administrator further in this Advice, but where appropriate the beneficiary of the estate can be substituted.
12. The benefit of making it clear that property passes, is that it makes it unlikely that there will later be a dispute in relation to ownership. Should the living relatives in future however wish to inspect an EMD, for example for the purposes of clinical negligence proceedings, the legal entity which at that time owns the EMD may still be subject to a disclosure and inspection request or order. In other words, simply because property in the EMD passes does not mean that third parties may not later acquire legal rights to inspect it.
13. There is no reason why this analysis should differ, because a Coroner requested the post-mortem, as opposed to it having taken place for a different reason. The property rights in the EMD are not affected by the different initiators for a post-mortem.

**What should the pathologist who has conducted the post-mortem do with the EMD?
Can they dispose of it or recycle it, or send it to another part of the world to be recycled?**

14. Plainly, where the executor or administrator requests that the EMD be handed over to be distributed with the rest of the estate, this must be done (as long as the EMD is no longer required by the Coroner, police or other relevant authority such as a Court, to be retained).
15. Where the administrator or executor has authorised the retention or disposal of the EMD, the EMD can and should be dealt with accordingly.
16. I assume that by “recycled”, this question asks whether such devices can be re-implanted into another person. There is no aspect of property law which prevents this occurring (although I would advise that such use is expressly authorised by the executor or administrator prior to property passing), but it is a question of medical and medico-ethical expertise, whether this would be an appropriate course of action to take. I cannot advise on whether such use of an EMD would be appropriate, because there would need to be relevant clinical expertise recommending such use, setting the boundaries as to when it would be appropriate to re-use EMDs. Medico-legal expertise may also be necessary to ascertain in particular whether the risks of trials to ascertain whether EMDs were safe to be re-used were sufficiently low so as to grant such trials ethical approval.

¹ The fact that the deceased’s property vests in an administrator or executor is a long established rule of probate law. See for instance *Dobbs v Brain* [1892] 2 QB 207 at 214.

17. The legal requirements in relation to the handling of medical waste would also need to be considered by any such experts advising on the issue.

Are there any further comments to be made on the draft Guidance?

18. I have carefully considered the draft Guidance and there are no other obvious issues upon which comment from a legal perspective appears necessary, but I am happy to advise on any specific questions which fall within my areas of work.

19. Please contact me by email or telephone in Chambers if I can assist further.

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17 February 2015

Annex

During the post-mortem examination of the Deceased, [name], a [specific EMD] was removed and retained.

I hereby authorise the following course of action in relation to the [specific EMD] (“the device”) (tick as appropriate):

- the device is to be given to me OR
- disposal of the device OR
- the property in the device is transferred to [e.g. XXX NHS Foundation Trust] for educational and training use
- the property in the device is transferred to [e.g. XXX NHS Foundation Trust] for re-use in another patient or patients, who may receive the device at a medical facility operated by a different body

[To be signed, dated and contain the contact details of the executor or administrator]