

## Guidelines for research work on sudden cardiac death: A Cuban proposal

Daisy Ferrer Marrero<sup>1,2</sup>✉, MD, MSc; Luis A. Ochoa Montes<sup>2,3</sup>, PhD; and Halina Pérez Álvarez<sup>2,4</sup>, MD, MSc

<sup>1</sup> Facultad de Ciencias Médicas Victoria de Girón, Universidad de Ciencias Médicas de La Habana. Havana, Cuba.

<sup>2</sup> Grupo de Investigación en Muerte Súbita de Cuba.

<sup>3</sup> Hospital Clínico-Quirúrgico Hermanos Ameijeiras. Havana, Cuba.

<sup>4</sup> Instituto de Medicina Legal. Havana, Cuba.

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✉ D Ferrer Marrero  
Blanquita 1706, bajos, e/ Segunda y  
Acosta. Casino Deportivo, Cerro  
10600, La Habana, Cuba.  
E-mail address:  
dferrer@infomed.sld.cu

### ABSTRACT

Heart diseases are nowadays the most frequent cause of premature death and disability in the world and future projections indicate that it should continue to be the leading cause in industrialized countries. There is a statistical underregistration of this disease in Cuba and from the existing estimates, a specific unexpected death rate of 105.2 per 100 thousand inhabitants is expected, equivalent to nearly 12.3% of natural deaths (one episode each 45 minutes). In most nations, the absence of protocols, strategies, guidelines and diagnostic algorithms, which methodologically guide data collection, remains an important limitation. Moreover, the non-standardization of criteria, in countries where there are guidelines for their study, contributes to the differences observed in the current reports of individual series. Hence practice guidelines for research work on sudden cardiac death are presented; showing the systematics to be developed and containing the main variables (necropsy studies and complementary investigation), to be used for research work on this disease in Cuba. This will allow data recording of sudden death and diseases that cause it (when they can be identified), with no other type of under-reporting.

**Key words:** Sudden cardiac death, Research, Registries, Practice guidelines, Clinical protocols.

### *Guía para trabajos de investigación en muerte súbita cardiovascular: Propuesta cubana*

### RESUMEN

Las enfermedades cardiovasculares constituyen actualmente la causa más frecuente de muerte prematura e invalidez en el mundo y las proyecciones futuras indican que debe seguir siendo la primera causa en los países industrializados. En Cuba existe un subregistro estadístico de esta enfermedad y a partir de las estimaciones realizadas se prevé una tasa específica de fallecimiento inesperado de 105,2 por cada 100 mil habitantes, lo que equivale aproximadamente al 12,3% de las muertes naturales (un episodio cada 45 minutos). En la mayoría de las naciones, la ausencia de protocolos, directrices, guías y algoritmos diagnósticos, que orienten metodológicamente la recogida de los datos, resulta una importante limitante; además, la no estandarización de criterios, en los países donde existen guías para su estudio, contribuye a las diferencias observadas en los informes actuales de series

*individuales. Por estas razones se presenta una guía para trabajos de investigación sobre muerte súbita cardiovascular, que muestra la sistemática a desarrollar y contiene las principales variables (estudios necróscos e investigaciones complementarias), para ser empleada en los trabajos de investigación sobre esta enfermedad en Cuba. Ello permitirá contar con el dato para el registro de la muerte súbita y de las enfermedades que la provocan (cuando se puedan identificar), sin que se produzca otro tipo de subregistro.*

**Palabras clave:** Muerte súbita cardíaca, Investigación, Sistema de Registros, Guías de Práctica Clínica, Protocolos clínicos

## BACKGROUND, JUSTIFICATION AND DESIGN

Cardiovascular diseases are currently the most frequent cause of premature death and disability in the world. Of an estimated 54.6 million deaths in 2011, according to a report published by the World Health Organization, 31.3% are related to deaths from heart and blood vessels diseases. In the Americas region, out of 6.3 million deaths, 1.8 million belong to this group of diseases<sup>1</sup>. Future projections indicate that this disease should continue to be the leading cause of death in industrialized countries and the third in those currently developing<sup>2</sup>. One in every two of these deaths result from one of the most striking and significant manifestations within ischemic heart disease: sudden cardiac death (SCD)<sup>3</sup>.

SCD is an enormous challenge because of its high incidence. Recent estimations based on current world population statistics ascribe nearly 4 to 5.35 million deceased to unexpected death every year in the world, which accounts for 14650 daily deaths and 10 events per minute<sup>4</sup>. About 400-450 thousand events per year<sup>5</sup> are estimated to occur only in Europe and the USA.

Along with this is the dramatic nature of its presentation, since SCD is not infrequent in young, seemingly healthy and occupationally active populations, which is one of the main causes of potentially lost years of life, bringing on serious family, economic and social effects<sup>6</sup>.

There is a statistical underreporting of this disease in Cuba. Despite being included in the Tenth International Classification of Diseases (ICD) (code I46.1)<sup>7</sup>, the majority of cases are not effectively diagnosed (in 2013, the cases reported are only 0.07% of the total registered natural deaths)<sup>8</sup>. At present, cardiovascular diseases are the second cause of death, with a rate increase of 100 thousand inhabitants from 148.2 in 1970 to 211.6 in 2014. From estimates based on information provided by the National Registry of Medical Records Executive and Health Statistics of

the Ministry of Public Health in 2014<sup>9</sup>, a specific unexpected death rate of 105.2 per 100 thousand inhabitants is calculated, adding up to, 12.3% of natural deaths (1 episode every 45 minutes). Epidemiological studies report 10% of natural deaths from SCD, rating 54.8 per 100 thousand inhabitants<sup>10</sup>.

Future effective surveillance of SCD remains affected by the way researchers approach the problem, starting from several known limitations in the clinical investigation of this disease, comprising non-standardization of criteria for case study, which must include not only post-mortem macroscopic and histological examination, but also clinical data to be procured because of their relevance<sup>6</sup>.

In most nations, the lack of protocols, guidelines, guides and diagnostic algorithms to methodologically manage data collection (socio-demographic, clinical and anatomopathological), is an important current limitation to be considered by researchers. The non-standardization of methodological criteria for the investigation of cases in countries where there are guidelines to study them, contributes to the differences observed in the present Individual series reports<sup>11</sup>.

### Background in Cuba

A methodology for the integral study of SCD was published in Cuba in 1998 by Falcón and Fernández-Britto<sup>12</sup>. It is an important tool for research purposes in Pathological Anatomy laboratories, aimed at the study of pathomorphology and morphometry of sudden death, which uses the atheometric system as a basic work tool: scientific method that allows qualitative and quantitative evaluation of the atherosclerotic lesion in any vascular sector and in its dependent organs, which also unifies the criteria of study, for the appreciation and information of the atherosclerotic process and its organic consequences<sup>13</sup>.

This 19 years old publication has some known limitations like not including unwitnessed SCD in the definition. Nor does it include the socio-demograph-

ic and clinical variables that must be studied, because of their importance and relation to this type of event. Besides, as it focuses on the pathomorphological and morphometric aspects of atherosclerotic lesion in sudden death, the specific methodological aspects of post-mortem study are excluded for this type of event; which, according to the article claim, "does not differ in the technical aspect from those usually performed" for other causes of death<sup>12</sup>. At present, other authors have provided similar documents adapted for use in the European Union and the West, which outline these aspects<sup>14,15</sup>.

This methodology does not make reference either to the mandatory complementary investigations on case screening: histopathological, toxicological, biochemical and genetic studies.

### **Problematic situation**

It is well known the important challenge SCD implies for health systems worldwide and for Cuba, given its high incidence and its family, economic and social impact. However, although we have a methodology for postmortem study of cases in Cuba, aimed to study the pathomorphology and morphometry of sudden death,<sup>12</sup> there are no means to methodically guide every step to be taken containing the main variables, post-mortem studies and complementary research to be included in research works on SCD.

### **Scientific problem**

What methodological value would have the development and application of a guide for research work on SCD, showing the systematics to be developed and containing every main variable, post-mortem studies and complementary research to use in the research work on this disease in Cuba?

### **Objective**

To propose a guide for research work on SCD showing the systematics to be developed and containing every main variable, post-mortem studies and complementary research to use in the research work on this disease in Cuba.

### **The Guide**

The guide starts with a group of definitions to adjust the framework (there are 7 items developed from the definition of SCD), within which is the definition of SCD; major and minor criteria used for its diagnosis<sup>15</sup>; time-based classification; criteria to define the time of onset of symptoms; some of the meanings used in the definition about dilemmas regarding the

issue; its character, occasionally, of suspicious death; and the accuracy of the definition taken into account for the draft guide, along with the criteria that justify the extended time period in the definition, as well as additional meanings to these criteria.

It also comprises inclusion and exclusion criteria, investigation stages and primary data collection model.

Within the inclusion criteria are those referred to death that:

- Occurs unexpectedly, witnessed, in an interval of up to 6 hours from the onset of premonitory symptoms<sup>11</sup>.
- Occurs unexpectedly, unwitnessed, in an interval of up to 24 hours; where all life-threatening non-cardiac causes have been ruled out<sup>11</sup>.
- The cases of natural death of cardiac origin in which the patient is placed under artificial supports, delaying death in a term greater than 6 hours<sup>16</sup>.

Primary data collection model primario (**Tabla**) has copyright and includes, in 14 chapters, 167 variables for SCD study, (30 socio-demographic, 124 clinical and 13 anatomopathological).

## **THREE STAGES IN THE INVESTIGATION**

Three stages<sup>17</sup> are considered, the one related to hospital work, the one related to verbal autopsy and the one derived from performing necropsy, either clinical or medicolegal. Information about death is obtained in stages I and II.

### **Stage I: Hospital work**

Stage I, which is aimed at evaluating the diagnostic hypothesis of a "sudden death", begins with the occurrence of a death due to biological (natural) causes at ages  $\geq 18$  years, in a person with cardiovascular disease (known or not), unexpected, or where there is some indication of a medical nature or not, which a priori prevents defining its etiology and ruling out its criminal origin.

This stage defines 10 objectives and the many sources for information gathering related to the inclusion criteria.

### **Stage II: Verbal autopsy**

The "verbal autopsy" is a technique for collecting information through an interview with family members close to the deceased and the doctor treating

the patient; whose use, in these cases, is based on the sudden and unexpected nature of the episode; since about 70% of cases are manifested in an out-of-hospital setting and, unwitnessed, in a third; thus an interview to detect any cardiovascular history and the causes of death makes it possible to obtain a greater amount of information, particularly when the death record is deficient or its causes are poorly registered<sup>18</sup>.

Likewise, the guide shows its two objectives and the three possible sources for obtaining information, identified by the authors, and the conditions for its application are added in order to guarantee data quality and homogeneity.

### Stage III: Methodology for necropsy

The importance of performing an autopsy, whether clinical or medicolegal, is unquestionable, but when it comes to the investigation of a death that has occurred in a healthy or apparently healthy subject, very often, young, in a short period of time, and with a brief evolution of the previous symptoms, if they existed; then, clarifying the death, its causes and

even its circumstances, becomes a challenge for the researcher.

It should be considered as a beginning in the knowledge of certain medical and social problems, and not as a final chapter in the history of life. We must bear in mind that it has different meanings for different people according to their relationship with the deceased; so it is not possible to initiate it without taking into account certain resources, procedures and conditions to guarantee it meets the objectives and benefits that justify it<sup>19,20</sup>.

It is an ethical obligation of the specialists that participate in an investigation, to know its details, which implies providing and paying attention to all of the recommendations; This is where we derive the options of whether cost-benefit analysis is appropriate or not, whether true informed consent has been practiced or not, and whether the expected results really benefit the people involved in the research, among other aspects<sup>21</sup>.

### Structure of the methodology content for necropsy

1. Relevant information when performing the nec-

**Table.** Structure of the Primary Data Collection Model - GIMUS (Acronym in Spanish: Sudden Death Research Group).

Chapter	Content	Type of variable	Nº variables
I.	Personal identity data	Socio-demographic	18
II.	Risk factors	Clinical	11
III.	Toxic habits	Clinical	5
IV.	Dietary habits and physical activity	Clinical	6
V.	Clinical examination	Clinical	7
VI.	Stress and personality	Clinical	3
VII.	Personal and family pathological background	Clinical	8
VIII.	Heart studies	Clinical	39
IX.	Data related to the event	Clinical	33
X.	Anatomopathological variables	Pathological	4
XI.	Study of the coronary arteries Application of the atheometric system	Pathological	9
XII.	Sudden Structural Coronary Death	Clinical	11
XIII.	Classification of sudden cardiac death	Clinical	1
XIV.	Socio-demographic factors	Socio-demographic	12
<b>Total variables</b>			<b>167</b>

ropsy:

- 1.1. Sources of information
- 1.2. Information to obtain
2. Autopsy procedures
  - 2.1. External examination of the body
  - 2.2. Internal examination of the body
  - 2.3. Macroscopic examination of the heart
  - 2.4. Application of the atherometric system
  - 2.5. Microscopic study of the heart
  - 2.6. Microscopic study of other organs and tissues
  - 2.7. Other diagnostic tests
3. Ethics and bioethics in research
4. Diagnosis on sudden death of cardiovascular origin.

### **Development of the methodology content**

#### **1. Relevant information when performing the necropsy**

Its purpose, content and meaning relate to the previous stages of the guide; but, being an intrinsic part of the post-mortem investigation itself, they are listed below.

It covers the sources of information, which are defined in them and conform to the inclusion criteria and the information that must be obtained in relation to the deceased and the event.

#### **2. Autopsy procedures**

In cases in which there is a suspicion of sudden death, in general, and of cardiovascular origin, in particular, it is essential to perform an autopsy (necropsy), either medicolegal (more frequently, as in many cases raises suspicion of criminality) or clinic, for which there are established guidelines<sup>14,15,22-25</sup>.

As a method of investigation of organs, tissues and liquids, it must be complete and systematic; so it is recommended, among other things, not to start it without complying with each condition required for its realization, to avoid unnecessary improvisation and waste of time, since it insists on the need to not waste time on aspects that may have been provided in advance<sup>26</sup>.

Thus we develop this section referring to autopsy procedures, since not only one must count all possible antecedents, but also suspect of anything difficult to diagnose, for an old saying goes that in medicine mathematics are not exact. Likewise, the existence of lesions in the possible entry doors should be ruled out, so that any finding in the corpse would be

surprising and so as not to lose evidence elements once the cavities are opened; To do this, it is necessary to carefully dissect and obtain the samples in a convenient way, since it is not possible to study what has not been previously seen<sup>14,15</sup>.

It is essential to visualize alterations and relationships before obtaining the samples for a diagnosis, since one precedes the other and determines it; as well as observing the conditions predicted in the samples collection for the different studies to be carried out, since histopathology fixation may contaminate the samples for the toxicological study or another one that is deemed necessary. It is important to fix the required image, according to the existing means; since a well-illustrated report is of greater value and usefulness; without overlooking the importance of histopathological report because of its diagnostic, suggestive or confirmatory value.

#### **External examination of the body**

General elements must include the identification signs of the corpse, description, exploration of death signs along with its chronology setting, musculoskeletal exploration if necessary, and natural orifices. Signs for corpse identification include age, not only recorded in the background but also in the examiner's opinion, and also length (height), weight, body habit and sex.

It is a detailed study which requires almost every alteration in the corpse: color and skin lesions, tattoos, malformations or deformities, scars, surgical interventions, malformation of natural orifices and others<sup>12,14,15,26</sup>.

Besides supporting it, the objectives of this examination and six typical procedures are included.

#### **Internal examination of the body**

For organs removal, an incision is usually made from the front of the neck to the symphysis pubis, which allows the thoracic and abdominal organs to be extracted in blocks. In the skull, an incision is made from ear to ear and the skin is removed to bony surface, which is opened with a saw or blade to extract the brain, with the cerebellum and the stem, as well as the pituitary gland. In case of suspicion of spinal cord injuries, this should also be removed.

Before and after removing these organs, the corporal cavities are examined (in situ exploration) in order to visualize the corresponding organs and their relations with observed alterations or within themselves; as well as in search of position anom-

lies or absences of organs, presence of fluid, adhesions or other alterations<sup>12,14,15,26</sup>.

Once the opening and exploration of the cavities is completed, the visceral block is dissected, as part of the necropsy, for which room conditions, clothing and instruments required must be taken into account, in compliance with the regulations established.

The internal examination allows the study of different organs in order to rule out causes of sudden death of non-cardiac origin, such as encephalic (among which hemorrhages stand out), respiratory (such as asthma or pneumonia), hemorrhages from different origin, shock, as well as digestive and renal diseases, among others.

To the general foundation, the formulation of accomplishment objectives and its 3-steps methodology items is united, where the possible evidence of other causes of sudden cardiac death stands out.

### Macroscopic examination of the heart

The macroscopic evaluation of the heart stands out as part of internal examination, which is essential, because a large number of heart diseases explain sudden death; either by electrical or mechanical mechanisms. Many of them, in turn, have macroscopic expression, such as arterial diseases causing ischemia, where it is accepted that the minimum degree of arterial disease that can be reasonably associated with death is an area of stenosis of 75%.<sup>27</sup>; without having a specific distribution pattern and where most often all vessels are affected.

Others that may cause sudden death and be explained through macroscopic examination are those related to myocardial and valvular damage<sup>12,14,15</sup>. Its objectives and procedures are defined in the guide for this exploration, to be carried out in 11 items, which are developed step by step, including the techniques and solutions to be used.

### Microscopic study of the heart

The previous examination is complemented with the microscopic study of the heart<sup>12,14,15</sup>. The pathologist or legal expert, depending on the case, taking into account antecedents, macroscopic description and preliminary conclusions, begins to observe every processed histological sections under the microscopy<sup>20</sup>; since must be borne in mind the contribution made to the diagnosis, and the observation of the English pathologist Bennett, in 1844, on the limitations of macroscopic pathology.

The samples of myocardium obtained for the mi-

croscopic study must be well selected, which allows their observation to narrate the case by itself. It is recommended to take the union between zones of normal and pathological aspect, since always continuous study shows the variability limits. Likewise, remnant preservation of the samples must be guaranteed until final conclusion.

Here the conditions and the procedure are detailed through 9 items, with sub-steps for their laboratory processing and subsequent interpretation.

### Microscopic study of other organs and tissues

Sudden death cannot be investigated through necropsy performance if it is not complete, so microscopic examination of other organs and tissues is essential, which promotes the exclusion of SCD as a cause of death, if causes of sudden death linked to other devices and systems are found<sup>14,15</sup>.

This section includes the objectives for this examination and details, in 6 items, its procedures, highlighting the possible evidence of other causes of sudden cardiac death.

### Other diagnostic tests

The study is complemented by other investigations, depending on the medical history and circumstances of death, all of the examinations that are considered necessary must be indicated, prior to formalin immersion of organs and tissues, because the supervision chain of the obtained samples and the fulfillment of every investigation stage in the laboratories must be guaranteed, constituting the quality guarantee of the preanalytical, analytical and post-analytical stages<sup>12</sup>.

The guide considers the performance conditions and 9 procedures comprising toxicological, biochemical and genetic studies.

### The atherometric system: an attach on structure<sup>28</sup>

The development and application of morphometric methods in the biomedical sciences has favored the knowledge of many diseases and has provided, at the same time, an adequate vehicle to compare results between different investigations, since the influence of evaluative subjectivity becomes less expressive<sup>28</sup>. According to Fernández-Britto *et al.*<sup>29</sup>, the emergence and development of atherometric system is framed with the publication, by Carlevaro and Fernández-Britto Rodríguez, in 1982, of «Metric aspects for the characterization of atherosclerotic lesion».

This method, developed and put into practice by

the Center for Research and Reference of Atherosclerosis in Havana<sup>28,30</sup>, provides a useful tool for qualitative and quantitative evaluation of atherosclerotic lesions in any vascular region and its dependent organs, and unifies the criteria of study, appreciation and information of the atherosclerotic process, as well as its organic consequences. This method has been used for the study of sudden death since 1985<sup>30,32</sup>.

It is a set of methods and procedures, through which a series of interdependent and strongly related variables are elaborated, resulting from biophysical reasoning and considerations (rheological, geometric, hemodynamic and mathematical); aimed at qualitatively and quantitatively analyzing the atherosclerotic lesions of any artery (arterial variables); as well as the lesions that, as a result, occur in the tissues and organs dependent on the irrigation of these vessels (organ-dependent variables). By measuring in millimeters (mm) of the arterial length and in mm<sup>2</sup> of the total endoarterial surface and of the areas occupied by fatty streaks, fibrous and severe plaques (set of primary arterial variables of this system), it allows to explore pathomorphologic and pathophysiological alterations, through the correct use of the variables and their different combinations.

The atheometric system, in the investigation of sudden death, is applied in the study of the coronary, carotid, aorta, iliac, femoral arteries and the polygon of Willis; as well as in the study of the heart or any other organ or artery that is required, according to the planned investigation design. The mentioned biophysical and mathematical principles of the system can be reviewed in articles previously published by Professor Fernández-Britto Rodríguez and his collaborators<sup>29,33</sup>.

Some steps and processes necessary in its application are included, which may be susceptible to technological improvements, as allowed by the scientific-technical development.

In the guide, the quantitative evaluation of the myocardium is deployed<sup>12,34</sup>, by means of descriptive and weighting variables for the arteries study (obtaining, definition, staining and measurements) and the qualitative and quantitative evaluation of the defined vascular sectors. Measurements to be carried out and analyzes deriving from them are detailed. The quantitative evaluation is done by applying the described criteria for the descriptive (volumetric) variables and the ponderative (atheometric indexes) organodependent factors of the atheometric system, which are used for the study of any or

gan.

The qualitative evaluation of the atherosclerotic process in the arteries is carried out according to the type of lesion and consists on classifying them, applying the atheometric system, which follows the World Health Organization classification, and considers 3 types of basic atherosclerotic lesions: fatty streak, fibrous plaque and severe plate<sup>13</sup>.

To carry out the quantitative evaluation of the atherosclerotic process in the arteries, a group of measurements is made that constitute the primary information from which the rest of the variables that make up the atheometric system are obtained. They can be done by any planimetric method; by means of a digitizer coupled to a computer, as is done in the Center for Research and Reference of Atherosclerosis of Havana (CIRAH), which has a program made for this purpose that transmits the information to a statistical package or; using an image software; the latter simplify the work and provide reliable information on the primary data<sup>13</sup>.

In this section, the variables to be registered, analyzed and compared are detailed.

### **3. Ethics and bioethics in research**

It cannot be ignored that, when developing all the manuals of organization and procedures (administrative, teaching or investigative), or proceed –in some way– to its regulation, the necessary ethical conduct to assume by any intervening in the process, between them and towards the others should be registered.

It should be noted that, within the functions of the specialists, it is explicitly stated that acting in accordance with the ethical and deontological norms that govern the exercise of the medical profession; but it must be borne in mind that these include teaching and research, among others, which also have ethical aspects to consider.

Any action on the corpse, whether anatomopathological or medicolegal, as it is in the case of sudden death, includes, at the outset, the general principles of medical ethics; as well as deontological and bioethical obligations derived from existing codes<sup>35-39</sup>.

From a general point of view, it is essential to refer to the 3 ethical principles considered in the Belmont Report, and that extend and apply beyond the research. Respect for people's dignity, known as the principle of autonomy (including ethical convictions), the principle of beneficence and justice, which require fairness in the distribution of bur-

dens and benefits<sup>21</sup>.

The bioethical principle of consent has its peculiarities, depending on whether it is a clinical or medicolegal autopsy; in the first, it is an express informed consent from part of the relatives of the deceased and in the second one, it behaves as such, when the application for the realization of the expertise by the competent authority materializes. It also becomes clear that respect for people's dignity requires giving the body, and even the fabric that is processed, the use and destination for which it is obtained, provided that quality is ensured at all stages of processing and diagnosis.

The particularities of medico-legal proceedings cannot be excluded, common to anyone called as expert<sup>21</sup>, who must proceed well and faithfully in the performance of his duties, with no other purpose than to discover and declare the truth; as well as confidentiality<sup>35,37</sup> which, in medico-legal cases, is not absolute, but is specifically limited to the judicial authority that ordered the preparation of the expert report.

It can be affirmed that in all these procedures the ethical principles or values of honesty, simplicity, respect, modesty, humanism, honesty and discretion, among others, are made manifest; without discriminating between one or the other actions. Sometimes, with more significance and impact than in any other medical action, due to the social repercussion of the fact that motivates the action and its consequences.

The Cuban principles of medical ethics<sup>38</sup> are also made manifest, fundamentally in those related to relations between workers. They could be added: objectivity, prudence, reflection, judgment, impartiality, truthfulness and honesty<sup>39,40</sup>. However, there are principles based on this relationship that are not modified, such as the use of clear language, respect for the victim and the non-

performance of harmful actions.

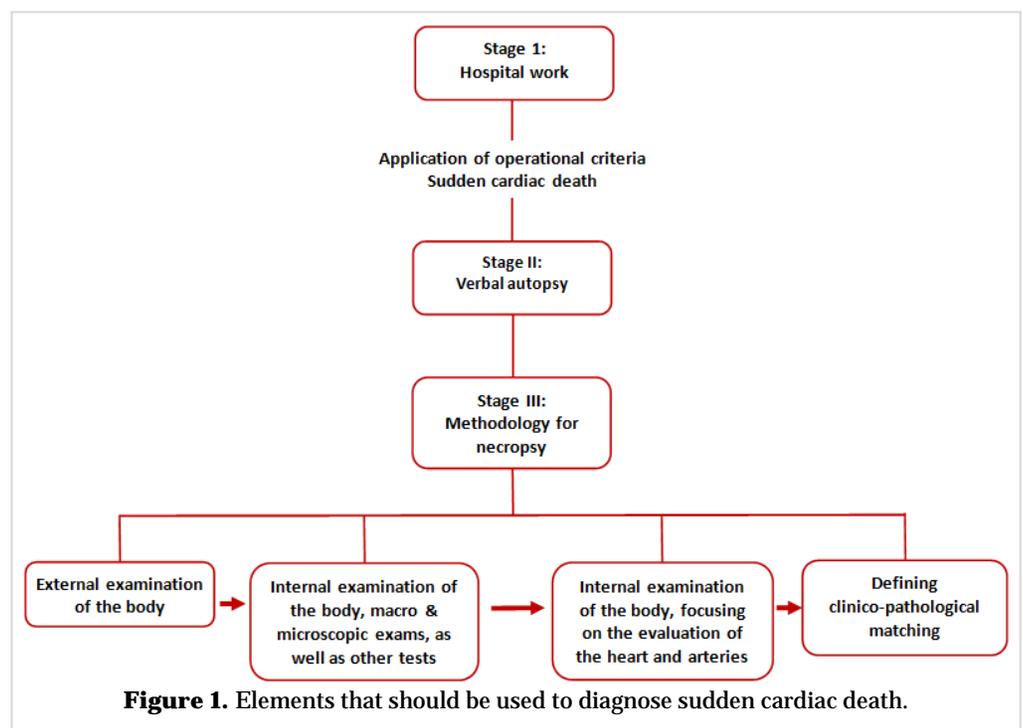
#### 4. The diagnosis of sudden cardiac death

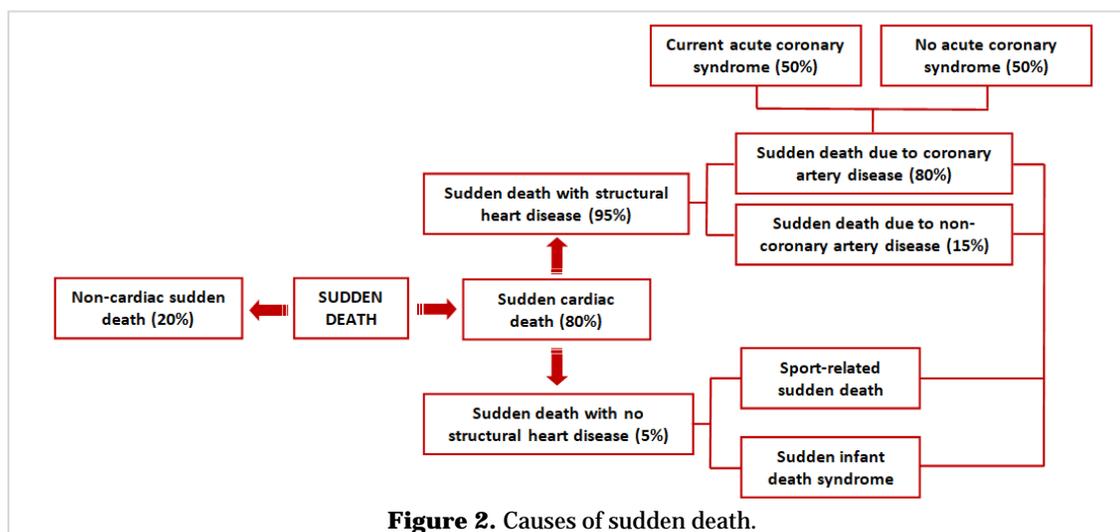
These autopsy procedures conclude with the diagnosis of SCD<sup>14,15</sup>, since it is important to establish it based on criteria that suggest its possibility, once elements of violence and other causes of sudden death have been excluded; and it is aimed at demonstrating the existence of arterial, valvular and myocardial diseases that make presume its diagnosis (**Figure 1**).

The Examination of the exterior of the body, as well as of its interior –with or without microscopic study or other investigations–, can establish the existence or not of signs of violence or other alterations that allow a diagnosis of non-cardiovascular cause of death, which facilitates the diagnostic algorithm.

The examination directed to the study of the heart and the arteries can show a cause of death of cardiovascular origin (**Figure 2**), ischemic or not; as well as arriving at the diagnosis of unexplained death (white or negative autopsies), of a functional nature with nonspecific post-mortem findings, such as heart rhythm disorders.

The researcher, when correlating the antecedents, preliminary macroscopic conclusions, analysis of the processed histological sections and the rest of





the carried out investigations' results, gives the final conclusions of the necropsy. Although much debated, whenever possible, the epicrisis or final assessment must be added, where a conclusion of the evolution and death of the patient is made, and the lack of correlation stands out –if it existed–<sup>41</sup>.

This means that the sequence of causes of death is established and must be adjusted to the certification<sup>42</sup>, when appropriate, as a direct cause, of SUD- DEN CARDIAC DEATH DUE TO ... (myocardial infarction, cardiac tamponade, aneurysm rupture, and others), if valid criteria for the establishment of its character of sudden death and of the causal disease were observed. This makes it possible to count on the data for the recording of sudden death and the diseases that cause it (when they can be identified), without any other type of under-reporting.

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