

病院外心肺停止患者記録(神戸版)

記録主体:神戸市消防局

集計協力:神戸大学医学部 災害・救急医学

記録開始:1999年4月1日

記録様式:「病院外心肺停止患者記録-大阪版-」に準拠

記録方法:

- 1) 搬送救急隊が、搬送時および病院到着後の所見、1か月後までの予後を記入する。
- 2) 救急救助課で集計し、記入漏れ等を点検する。
- 3) 神戸大学でコンピューター入力して詳細な点検を行ない、CPAに至った原因や、1か月後以降の予後について、監察医、初期治療病院、転院先病院に問い合わせる。

Out-of Hospital Cardio-Pulmonary Arrest in Kobe

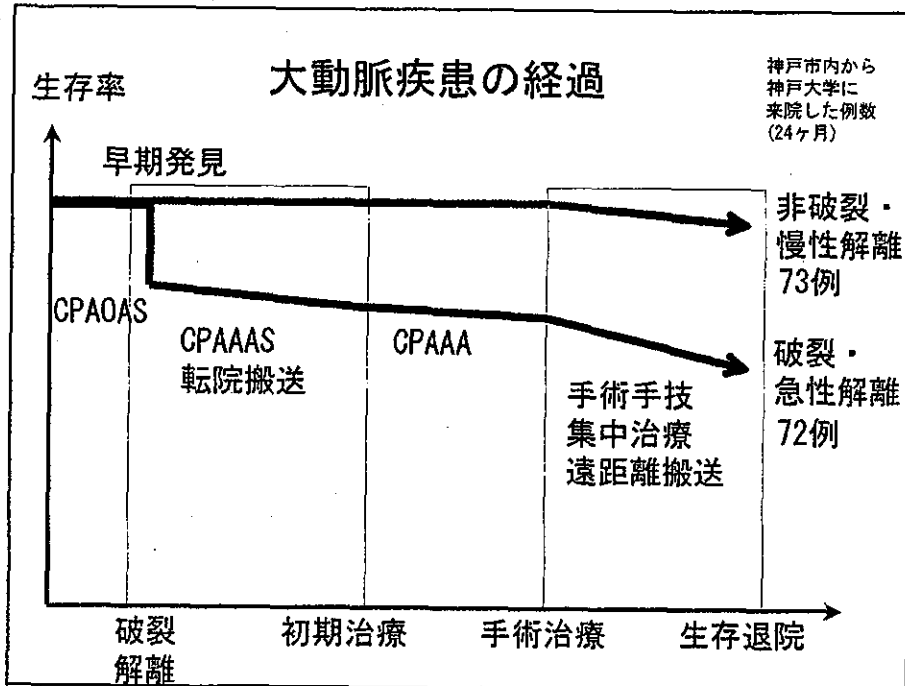
1999.4-2002.3 Kobe Fire Bureau

			Survival		
			24hours	1week	1month
External	552 (23%)	13.8%	9.1%	6.3%	
Cardiac	1139 (48%)	10.4%	6.9%	4.8%	
Respiratory	218 (9%)	11.9%	6.9%	3.2%	
CNS	186 (8%)	25.8%	10.8%	4.8%	
Others	292 (12%)	5.8%	3.8%	1.7%	
Total	2387 (100%)	12.0%	7.3%	4.0%	
Aorta	88 (3.7%)	1.1%	0.0%	0.0%	
Pulm. Embolism	25 (1.0%)	12.0%	8.0%	5.6%	

院外心肺停止患者の診断 (剖検)

Population-based
神戸市消防局
1999.4-2001.3

	内因性 院外心肺停止	剖検	大動脈
神戸市全体	1262	371 (29.4%)	65 (5.2%)
神戸大学以外	986	211 (21.4%)	40 (4.1%)
神戸大学	276	160 (58.0%)	25 (9.1%)



平成 16 年 1 月 6 日開催 第一回班会議資料

資 料

Cardiac Arrest and Cardiopulmonary Resuscitation Outcome Reports

Update and Simplification of the Utstein Templates for Resuscitation Registries

A Statement for Healthcare Professionals From a Task Force of the International Liaison Committee on Resuscitation (American Heart Association, European Resuscitation Council, Australian Resuscitation Council, New Zealand Resuscitation Council, Heart and Stroke Foundation of Canada, InterAmerican Heart Foundation, Resuscitation Councils of Southern Africa)

Ian Jacobs, MD, Co-Chair; Vinay Nadkarni, MD, Co-Chair; and the ILCOR Task Force on Cardiac Arrest and Cardiopulmonary Resuscitation Outcomes

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Abstract—Outcome after cardiac arrest and cardiopulmonary resuscitation is dependent on critical interventions, particularly early defibrillation, effective chest compressions, and advanced life support. Utstein-style definitions and reporting templates have been used extensively in published studies of cardiac arrest, which has led to greater understanding of the elements of resuscitation practice and progress toward international consensus on science and resuscitation guidelines. Despite the development of Utstein templates to standardize research reports of cardiac arrest, international registries have yet to be developed. In April 2002, a task force of the International Liaison Committee on Resuscitation (ILCOR) met in Melbourne, Australia, to review worldwide experience with the Utstein definitions and reporting templates. The task force revised the core reporting template and definitions by consensus. Care was taken to build on previous definitions, changing data elements and operational definitions only on the basis of published data and experience derived from those registries that have used Utstein-style reporting. Attention was focused on decreasing the complexity of the existing templates and addressing logistical difficulties in collecting specific core and supplementary (ie, essential and desirable) data elements recommended by previous Utstein consensus conferences. Inconsistencies in terminology between in-hospital and out-of-hospital Utstein templates were also addressed. The task force produced a reporting tool for essential data that can be used for both quality improvement (registries) and research reports and that should be applicable to both adults and children. The revised and simplified template includes practical and succinct

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operational definitions. It is anticipated that the revised template will enable better and more accurate completion of all reports of cardiac arrest and resuscitation attempts. Problems with data definition, collection, linkage, confidentiality, management, and registry implementation are acknowledged and potential solutions offered. Uniform collection and tracking of registry data should enable better continuous quality improvement within every hospital, emergency medical services system, and community. (*Circulation*. 2004;110:3385-3397.)

Key Words: AHA Scientific Statements ■ cardiopulmonary resuscitation ■ heart arrest ■ defibrillation ■ registries

The outcome of cardiac arrest and cardiopulmonary resuscitation (CPR) is dependent on critical interventions, particularly early defibrillation, effective chest compressions, and assisted ventilation. Despite considerable efforts to improve the treatment of cardiac arrest, most reported survival outcome figures are poor. If patient outcomes are to improve, then evaluation of the contribution of all of the potential risk factors and interventions is essential. Such evaluation has been hindered by the lack of accurate data on structure, process, and outcome of care, in part because of the lack of uniformity in defining and reporting results.

To improve this situation, the International Resuscitation Council Task Forces, now known as the International Liaison Committee on Resuscitation (ILCOR), published a series of guidelines for uniform reporting of adult out-of-hospital, pediatric, and adult in-hospital resuscitation and resuscitation education and animal research.¹⁻⁴ Utstein-style guidelines and templates also were prepared for reporting resuscitation outcomes after trauma and drowning.^{5,6}

The Utstein-style definitions and reporting templates have been used extensively in published outcome studies of cardiac arrest. The use of these tools has contributed to a greater understanding of the elements of resuscitation practice and has facilitated progress toward an international consensus on science and resuscitation guidelines.

Although the Utstein-style reporting template has many benefits, it also has several limitations. Fredriksson and colleagues⁷ recently reviewed published studies on outcomes after cardiac arrest that reported the use of Utstein-style templates. Many of these studies identified the complexity of the existing templates and logistical difficulties in collecting some of the recommended core and supplementary data elements. For example, it is difficult for rescuers to estimate and record specific intervals accurately during the resuscitation event. It is often not possible to ascertain elements such as time of collapse for unwitnessed arrests and survival outcomes at 6 months or 1 year after hospital discharge. Furthermore, inconsistencies in terminology between in-hospital and out-of-hospital Utstein templates prevent the adequate integration and comparison of individual research studies. In addition, the most recent international guidelines for resuscitation recommended important changes in the practice of resuscitation, some of which affect the validity of the existing Utstein definitions. Two examples of changes in practice that necessitate revision of the Utstein templates are the removal of the pulse check by non-healthcare providers as a criterion for defining cardiac arrest and the provision for attempted defibrillation by bystanders.⁸

In April 2002, an ILCOR task force met in Melbourne, Australia, to review and revise the Utstein definitions and reporting templates. To identify potential changes to data elements, the task force reviewed published data and experience from cardiac arrest registries that have used Utstein-style reporting templates. The task force used a modified Delphi methodology established by previous Utstein-style conferences to review data and achieve consensus on the following elements:

- Data registries
- Utstein templates
- Operational definitions
- Time issues
- Report elements and format
- Data linkage
- Data access, management, and confidentiality issues
- Registry implementation issues

Data on cardiac arrest outcomes are generally collected and reported in 2 different formats: a registry, which is used for quality improvement, and a research report, which examines specific interventions and outcomes. The objective of the task force was to develop a single, simple, and practical template for uniform collection and reporting of data on cardiac arrest. Uniform collection and tracking of data facilitate better continuous quality improvement within hospitals, emergency medical services (EMS) systems, and communities. They also enable comparisons across systems for clinical benchmarking to identify opportunities for improvement. The revised template includes practical and succinct operational definitions that synthesize what has been learned from the previous Utstein reporting guidelines and existing cardiac arrest registries. The revised template should lead to better and more accurate reporting of cardiac arrests and resuscitation attempts. The revised template will be suitable for recording resuscitation attempts in both adults and children.

Utstein Definitions

The authors of the 1991 Utstein publication wrote that "the nomenclature of cardiac arrest presents a classic problem in semantics," and added that "the Utstein definitions and recommendations attempt to solve this problem by presenting consensus definitions."¹ The task force reviewed the current definitions and updated them when appropriate to address challenges encountered with the use of these definitions and to conform with the recommendations of the *Guidelines 2000 for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care—An International Consensus on Science*.⁸ The definitions that were satisfactory and consistent with current practice were not changed. Following are definitions of the 29 core data elements as agreed on by consensus.

Arrest, Witnessed

A witnessed cardiac arrest is one that is seen or heard by another person or an arrest that is monitored.

Assisted Ventilation

Assisted ventilation is the act of inflating a patient's lungs by rescue breathing with or without a bag-mask device or any other mechanical device.

Attempted Defibrillation

Defibrillation can be attempted by means of an automated external defibrillator (AED), a semiautomated external defibrillator, an implantable cardioverter-defibrillator (ICD), or a manual defibrillator. The type of device used is not considered a core data element.

Bystander CPR

Bystander CPR is CPR performed by a person who is not responding as part of an organized emergency response system approach to a cardiac arrest. Physicians, nurses, and paramedics may be described as performing bystander CPR if they are not part of the emergency response system involved in the victim's resuscitation.

Cardiac Arrest

Cardiac arrest is the cessation of cardiac mechanical activity as confirmed by the absence of signs of circulation. If an EMS provider or physician did not witness the cardiac arrest, then the professional may be uncertain as to whether a cardiac arrest actually occurred.

Cause of Arrest (Etiology)

An arrest is presumed to be of cardiac etiology unless it is known or likely to have been caused by trauma, submersion, drug overdose, asphyxia, exsanguination, or any other non-cardiac cause as best determined by rescuers.

Chest Compressions

Chest compressions are performed by an individual or a mechanical device during CPR in an attempt to restore spontaneous circulation.

Cardiopulmonary Resuscitation

CPR is an attempt to restore spontaneous circulation by performing chest compressions with or without ventilations.

Date of Arrest

The date of arrest is the date the event was known to occur or the date on which a patient was found. This date should be recorded in a conventional format that is consistent for the region (eg, YYYY, MM, DD; DD, MM, YYYY; or MM, DD, YYYY).

Date of Birth/Age

If a patient's date of birth is known, it should be recorded in an acceptable format. If the date of birth is not known but the patient's age is known, then the age should be recorded. If the patient's age is not known, his or her age should be estimated and recorded.

Date of Discharge/Death

The date of discharge or death is the date on which the patient was discharged from the acute hospital or was certified dead. It should be recorded in an acceptable format.

Defibrillation Attempt Before EMS Arrival

When a bystander attempts defibrillation (eg, public access or layperson rescuer defibrillation), it is recorded as a defibrillation attempt before EMS arrival. AEDs are increasingly being made available to the public. In patients with an ICD, a shockable rhythm is likely to have triggered ≥ 1 shock by the device before the arrival of EMS personnel. This shock can be confirmed by analyzing the ICD memory. After extensive discussion, the task force agreed that defibrillation attempts via ICDs are important but difficult for EMS to track. Thus, ICD documentation is optional.

Drugs

The term "drugs" refers to the delivery of any medication (by intravenous cannula, intraosseous needle, or tracheal tube) during the resuscitation event.

Emergency Medical Services

EMS personnel respond to a medical emergency in an official capacity as part of an organized medical response team. By this definition, physicians, nurses, or paramedics who witness a cardiac arrest and initiate CPR but are not part of the organized rescue team are characterized as bystanders and are not part of the EMS system.

End of Event

A resuscitation event is deemed to have ended when death is declared or spontaneous circulation is restored and sustained for 20 minutes or longer. If extracorporeal life support is being provided, then the end of event is 20 minutes after extracorporeal circulation has been established.

First Monitored Rhythm

The first monitored rhythm is the first cardiac rhythm present when a monitor or defibrillator is attached to a patient after a cardiac arrest. If the AED does not have a rhythm display, then it may be possible to determine the first monitored rhythm from a data storage card, hard drive, or other device used by the AED to record data. If the AED has no data-recording device, then the first monitored rhythm should be classified simply as shockable or nonshockable. This data point can be updated later if the AED has data download capability.

Location of Arrest

Location of arrest is the specific location where the event occurred or the patient was found. Knowledge of where cardiac arrests occur may help a community to determine how it can optimize its resources to reduce response intervals. A basic list of predefined locations will facilitate comparisons. Local factors such as the following may make the creation of subcategories useful:

- Place of residence (eg, home, apartment, back yard of a home)

- Public place (eg, street, city park, shopping center, sports stadium, entertainment center, airport, railway station, church, beach, office building)
- Other (eg, hotel room, private office, long-term care facility)

Neurological Outcome at Discharge From Hospital

Documentation of a patient's neurological status at many specific points is desirable (eg, on discharge from the hospital, at 6 months, at 1 year); however, recording neurological outcomes after discharge has been difficult. Survival without higher neurological function is suboptimal; therefore, it is important to attempt to assess neurological outcome at discharge. A simple validated neurological score such as the Cerebral Performance Category (CPC) should be recorded, if available.⁹

Patient Identifier

A patient identifier is a unique numeric or alphanumeric sequence that identifies a specific patient and cardiac arrest event. Ideally, the patient identifier should stay with the patient from the resuscitation event to hospital discharge (recovery or death). Unfortunately, few systems have the ability to link individual patient care records for the out-of-hospital, in-hospital, and postdischarge phases of the event.

Resuscitation

A resuscitation attempt is defined as the act of attempting to maintain or restore life by establishing or maintaining airway (or both), breathing, and circulation through CPR, defibrillation, and other related emergency care techniques.

Resuscitation Attempt by EMS Personnel

When EMS personnel perform CPR or attempt defibrillation, it is recorded as a resuscitation attempt by EMS personnel.

Resuscitation Not Attempted by EMS Personnel

EMS personnel may not attempt resuscitation when a do-not-attempt-resuscitation (DNAR) order exists, a resuscitation attempt is considered futile, or resuscitation is not required (eg, the patient shows signs of circulation).

Return of Spontaneous Circulation

Signs of the return of spontaneous circulation (ROSC) include breathing (more than an occasional gasp), coughing, or movement. For healthcare personnel, signs of ROSC also may include evidence of a palpable pulse or a measurable blood pressure. For the purposes of the Utstein registry template, "successful resuscitation" or ROSC is defined for all rhythms as the restoration of a spontaneous perfusing rhythm that results in more than an occasional gasp, fleeting palpated pulse, or arterial waveform. Assisted circulation (eg, extracorporeal support such as extracorporeal membrane oxygenation or a biventricular assist device) should not be considered ROSC until "patient-generated" (ie, spontaneous) circulation is established. Previous reports that focused on outcomes from

ventricular fibrillation have variably defined "successful defibrillation" as the termination of fibrillation to any rhythm (including asystole) and the termination of fibrillation to an organized electrical rhythm at 5 seconds after defibrillation (including pulseless electrical activity [PEA]). Neither of these definitions of successful defibrillation would qualify as ROSC unless accompanied by evidence of restored circulation. By consensus, the phrase "any ROSC" is intended to represent a brief (approximately >30 seconds) restoration of spontaneous circulation that provides evidence of more than an occasional gasp, occasional fleeting palpable pulse, or arterial waveform. The time at which ROSC is achieved is a core data element.

Sex

Sex (male or female) may be an important risk factor for cardiac arrest and resuscitation interventions.

Shockable/Nonshockable Rhythm

Shockable/nonshockable rhythm refers to the first monitored rhythm, which when analyzed by the person interpreting the monitor/defibrillator or an AED, was found to be treatable by attempted defibrillation (ie, shockable or nonshockable). In general, shockable cardiac arrest rhythms are further divided into ventricular fibrillation and pulseless ventricular tachycardia. Nonshockable cardiac arrest rhythms can be categorized as either asystole or PEA. Although a specific definition of asystole is desirable, no consensus agreement was reached on either a specific duration (eg, 30 seconds) or heart rate (eg, <5 bpm) to define asystole versus bradycardia/PEA. In future iterations of the registry document, further consideration and additional research resources may need to be devoted to addressing the importance and ability of providers to differentiate between these initial cardiac rhythms.

Successful CPR Before EMS Arrival

Occasionally when a bystander witnesses a cardiac arrest and starts CPR, the patient will regain signs of circulation by the time EMS personnel arrive. If the bystander verifies that the patient had no signs of circulation and that CPR was performed, a registry record should be initiated. EMS personnel do not need to verify that a cardiac arrest occurred for this case to be included in the registry.

Survived Event

"Survived event" for the out-of-hospital setting means sustained ROSC with spontaneous circulation until admission and transfer of care to the medical staff at the receiving hospital. For the in-hospital setting, survived event means sustained ROSC for >20 minutes (or the return of circulation if extracorporeal circulatory support is applied).

Survival to Hospital Discharge

Survival to hospital discharge is the point at which the patient is discharged from the hospital's acute care unit regardless of neurological status, outcome, or destination.

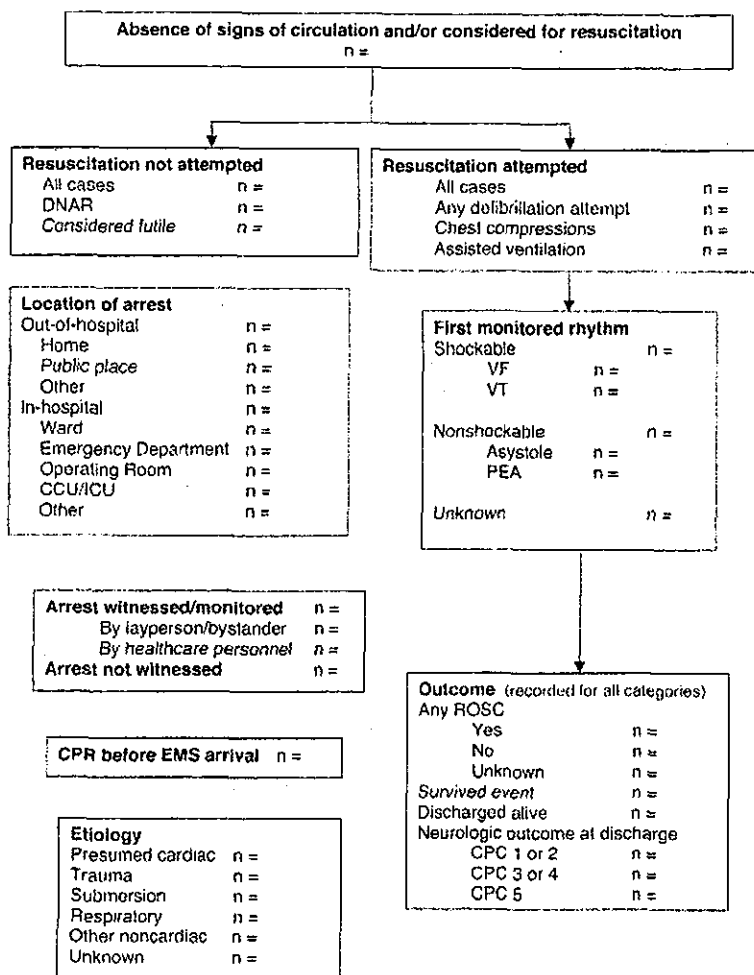


Figure 1. Utstein reporting template for core data elements. ED indicates emergency department; OR, operating room; CCU/ICU, critical care unit/intensive care unit; and PEA, pulseless electrical activity. Other abbreviations as in text.

Ideally, this should indicate survival to discharge from acute hospital care, including a possible rehabilitation period in a local hospital before long-term care, home care, or death.

Sustained ROSC

Sustained ROSC is deemed to have occurred when chest compressions are not required for 20 consecutive minutes and signs of circulation persist (or sustained ROSC if extracorporeal circulatory support is applied). Thus, after resuscitation from in-hospital cardiac arrest, sustained ROSC and survived event have the same definition.

Utstein Reporting Templates

The 1991 out-of-hospital and the 1997 in-hospital Utstein templates were comprehensive documents that were targeted mainly to the research community.^{1,2} The definitions in these documents have helped to standardize resuscitation terminology, although the capture of numerous data items is difficult for many individuals and institutions.

The task force discussed problems with the collection of resuscitation data extensively and assessed the usefulness of collecting data elements that were deemed important because of their potential impact on outcome but were difficult to collect or their accuracy was questionable (eg,

time of collapse). Of equal concern were data items deemed to have relatively little direct impact on outcome and yet were reliable and easy to collect (eg, time at which the EMS vehicle stopped).

The previous adult Utstein templates focused on witnessed ventricular fibrillation (VF) arrests. One reason to focus on witnessed VF was to provide a suitable comparator for judging the success of systems nationally and internationally. Unfortunately, a large and growing proportion of out-of-hospital arrests and the majority of in-hospital arrests present with a non-VF rhythm.^{10,11} The Utstein experts agreed that the revised template should include all initial cardiac arrest rhythms but retain the ability to analyze the witnessed VF subgroup for comparing systems. The 1991 Utstein document divided data into core and supplementary items, whereas the 1997 templates used slightly different terminology: essential and desirable. The revised Utstein template emphasizes only core data elements for registry use (Figure 1). The changes between earlier and revised Utstein templates are summarized in the Table.

Consensus Recommendation

Data should be classified as core or supplementary. Core data are the absolute minimum data required for continual

Utstein Data Templates: Summary of Changes

	1991 Name	2004 Name	2004 Definition	1991 Status	2004 Status
1.	Population served by EMS system	Removed	Total population of service area of EMS system	Core	Supplementary
2.	Confirmed cardiac arrests considered for resuscitation	Absence of signs of circulation and/or considered for resuscitation	Number of cardiac arrests defined by absence of signs of circulation	Core	Core
3.	Resuscitations not attempted	Unchanged	Total number of cardiac arrests in which resuscitation was not attempted and number of arrests in which resuscitation was not attempted because: <ul style="list-style-type: none"> • DNAR order was present • Attempt was considered futile (or meaningless) • Signs of circulation were present 	Core (total not attempted) None (DNAR and futile status)	Core
4.	Resuscitations attempted	Unchanged	Total number of resuscitations attempted and number of these resuscitations that included <ul style="list-style-type: none"> • Any defibrillation attempt • Chest compressions • Ventilations 	Core (total attempted) None (defibrillation, chest compressions, and ventilations)	Core
5.	Cardiac etiology	Etiology	Number of resuscitations in which etiology of arrest was <ul style="list-style-type: none"> • Presumed cardiac • Trauma • Submersion • Respiratory • Other noncardiac • Unknown 	Core	Core
6.	Noncardiac etiology	Merged with Etiology	See Etiology	Core	See Etiology
		Arrest witnessed/monitored	Total number of resuscitation attempts and number of arrests witnessed by <ul style="list-style-type: none"> • Laypersons • Healthcare providers 	None	Core
7.	Arrest witnessed by bystanders	See Arrest witnessed/monitored	Number of resuscitation attempts in which arrest was witnessed by laypersons	Core	Core
8.	Arrest not witnessed	See Arrest witnessed/monitored	Number of resuscitation attempts in which arrest was not witnessed by anyone	Core	Core
9.	Arrest witnessed by EMS personnel	See Arrest witnessed/monitored	Number of resuscitation attempts in which arrest was witnessed by healthcare personnel	Core	Core
		First monitored rhythm shockable	Total number of resuscitation attempts in which first monitored rhythm was shockable and identified as <ul style="list-style-type: none"> • VF • VT • Unknown AED-shockable rhythm 	None	Core
10.	Initial rhythm VF	See Monitored rhythm shockable	Number of resuscitation attempts in which first monitored rhythm after arrest was VF	Core	Core
11.	Initial rhythm VT	See Monitored rhythm shockable	Number of resuscitation attempts in which first monitored rhythm after arrest was VT	Core	Core
		First monitored rhythm nonshockable	Total number of resuscitation attempts in which first monitored rhythm was nonshockable and rhythm was identified as <ul style="list-style-type: none"> • Asystole • PEA • Bradycardia • Other • Unknown AED-nonshockable rhythm 	None	Core

Continued

	1991 Name	2004 Name	2004 Definition	1991 Status	2004 Status
12.	Initial rhythm asystole	See First monitored rhythm nonshockable	Number of resuscitation attempts in first monitored rhythm after arrest was asystole	Core	Core
13.	Other initial rhythms	See First monitored rhythm nonshockable	Number of resuscitation attempts in which first monitored rhythm after arrest was unshockable	Core	Core
14.	Determine presence of bystander CPR: yes or no for each subset	CPR before EMS	Number of resuscitation attempts in which CPR (chest compression) was performed before EMS arrival	Core	Core
		Rhythm analysis or defibrillation before EMS	Number of resuscitation attempts in which either AED rhythm analysis or defibrillation was performed before EMS arrival	None	Core
15.	Any ROSC	Any ROSC	Number of resuscitation attempts in which any ROSC was present: • Yes • No • Unknown	Core	Core
16.	Never achieved ROSC	See Any ROSC	See Any ROSC	Core	See Any ROSC
17a.	Efforts stopped: patient died en route to hospital	Removed	Number of resuscitation attempts in which all resuscitative efforts were discontinued and patient died before arriving at hospital	Core	Supplementary
17b.	Efforts stopped: patient died in ED	Removed	Number of resuscitation attempts in which all resuscitative efforts were discontinued and patient died in ED	Core	Supplementary
18.	Admitted to ICU/ward	Survived event to ED/ICU	Number of resuscitation attempts in which patient regained signs of circulation and was admitted to ED or ICU	Core	Core
19a.	Died in-hospital total	Removed	Number of resuscitation attempts in which patient regained signs of circulation and was admitted to ED/ICU but died in hospital	Core	Supplementary
19b.	Died in hospital within 24 h	Removed	Number of resuscitation attempts in which patient regained signs of circulation and was admitted to ED/ICU but died in hospital within 24 h	Core	Supplementary
20.	Discharged alive	Unchanged	Number of resuscitation attempts in which patient regained signs of circulation, was admitted to ED/ICU, and was discharged from hospital alive	Core	Core
21.	Died within 1 year after hospital discharge	Removed	Number of resuscitation attempts in which patient regained signs of circulation, was discharged alive from hospital but died within 1 year after hospital discharge	Core	Supplementary
22.	Alive at 1 year	Removed	Number of resuscitation attempts in which patient regained signs of circulation, was discharged alive from hospital, and was alive at 1 year after hospital discharge	Core	Supplementary
		Neurological outcome at discharge	Number of resuscitation attempts in which patient regained signs of circulation, was discharged alive from hospital, and had CPC score of • 1 or 2 • 3 or 4 or unknown	None	Core
		Location of arrest: out of hospital	Total number of resuscitations that took place out of hospital and number of resuscitation attempts that took place within • Home/residence • Industrial/workplace • Sport/recreation event • Street/highway • Public building • Assisted living/long-term care facility • Educational institution • Other • Unspecified/unknown	None	Core (EMS only)
	Location of arrest: in hospital	Total number of resuscitation attempts that took place in hospital and number of resuscitation attempts that took place within • Ward • Emergency Department • Operation Room • Intensive or Coronary Care Unit • Other • Unknown	None	Core (hospital only)	

Cardiac Arrest Data Collection Form			
Date of arrest YYYY/MM/DD			
Patient identifier (first name, last name, or ID number)			
Sex			
Age	years (estimated) OR Date of birth YYYY/MM/DD		
Cardiac arrest determined by			
Cause of arrest			
Treatment before EMS arrival			
<table border="1"> <tr> <td>Bystander CPR</td> </tr> <tr> <td>Defibrillation by bystander <input type="checkbox"/> or implanted defibrillator <input type="checkbox"/></td> </tr> </table>		Bystander CPR	Defibrillation by bystander <input type="checkbox"/> or implanted defibrillator <input type="checkbox"/>
Bystander CPR			
Defibrillation by bystander <input type="checkbox"/> or implanted defibrillator <input type="checkbox"/>			
Resuscitation attempted by EMS			
Location of arrest	out of hospital in hospital		
Witnessed	If witnessed, time of arrest HH:MM		
Initial rhythm			
Chest compressions			
Defibrillation attempt			
Ventilation	Drugs		
Time of collapse HH:MM (estimated)			
Time of call receipt HH:MM			
Time vehicle stopped HH:MM			
Time of first rhythm analysis HH:MM			
Spontaneous circulation (on arrival in ED)			
Hospital admission			
Hospital discharge			
Date of hospital discharge (or death) YYYY/MM/DD			
Neurologic status at discharge (CPC)			

Figure 2. Revised Utstein cardiac arrest data collection form.

quality improvement. These data form the data set for CPR registries at local, state/provincial, national, and international levels. They should be relatively easy to collect and reliable and include patient, event (process), and outcome data. Collection of these data elements should be sufficient to enable comparisons of process and outcomes among different institutions and countries. Supplementary data are required for resuscitation research. The standardized definitions enable comparative analysis between resuscitation studies. The task force agreed that a single data collection form should be used for both out-of-hospital and in-hospital cardiac arrest; an example is given in Figure 2.

Dates, Time Points, and Intervals

The 2 most important intervals affecting patient survival are the collapse-to-first CPR attempt interval and collapse-to-first defibrillatory shock interval.¹²⁻¹⁸ In the original Utstein document, many other time points and intervals

were recommended as core items for research and quality assurance purposes. Several of these time elements were included because of their known association with outcomes; others were included because they are relatively easy to document accurately and may be useful for quality assurance. These other times include when the emergency vehicle stops at the scene, the resuscitation team arrives at the patient's side, intravenous access is obtained, medications are given, and sustained ROSC is first attained.

The use of these clearly defined resuscitation intervals has improved resuscitation research as well as hospital and EMS quality assurance programs; however, few epidemiological studies and even fewer EMS and hospital systems have included the entire recommended list of core time elements. The supplementary list is used rarely. Time points such as estimated time of collapse when the arrest was not witnessed are impossible to obtain, and others are inherently unclear, such as when the hospital resuscitation team arrives (members arrive at different times).

Clock inaccuracy and lack of clock synchronization continue to be a problem. To minimize timing errors, the task force recommends that one clock (or one synchronized to the initial clock) be used to determine all times throughout the resuscitation attempt. It is more important to record intervals than specific times accurately.

The goal of the task force was to distinguish the time points and intervals that constitute core elements from those that represent supplementary data elements. Comparison of these elements enables comparison among research investigations and quality assurance programs. The following sections name the recommended time point/intervals to be collected and recorded in an acceptable format (HH:MM or similar).

Recommended Core Time Events to Be Recorded

Date of Death

The date of death should be recorded in a conventional format.

Time of Witnessed/Monitored Arrest

An arrest is witnessed if the collapse was seen (or heard) by an identifiable witness and monitored if a medical professional or electronic monitoring device detects and documents apparent cardiac arrest or the potential need for resuscitation.

Time When Call Received

The time that the first EMS operator was contacted should be listed as the time that the call was received. In the hospital the comparable time is when the resuscitation team is called after initial determination of the potential need for resuscitation. In some hospital settings (eg, intensive care unit, emergency department, operating room), this time may be when the bedside practitioner notes an arrest or the potential need for resuscitation and shouts for help. In other hospital settings, it may be when a nurse, ward clerk, or physician calls the operator to notify the cardiac arrest team. If a resuscitation team is called to evaluate a critically ill patient before an arrest or the need for resuscitation and the patient has an arrest in the presence of the team, then the time of call receipt is the same as the time of witnessed collapse/arrest.

Time of First Rhythm Analysis/Assessment of Need for CPR

This time is defined as when (1) cardiac rhythm is analyzed for a shockable rhythm or when (2) a provider clinically assesses the need for CPR (eg, no signs of circulation in the setting of a respiratory arrest or drowning). Under most circumstances this is the time when an AED or other defibrillator is attached to the patient and turned on. For in-hospital patients undergoing continuous ECG monitoring, this is the time when a provider attempts to interpret the ECG for evidence of a shockable rhythm.

Several reasons exist for adding this element to the previous core element of time to defibrillation. Evidence is accumulating that for prolonged VF, rhythm analysis and CPR before defibrillation may be preferable to immediate defibrillation.^{19,20} Moreover, many patients in cardiac

arrest or in need of CPR are not in VF. Under each circumstance, time of first rhythm analysis/assessment of CPR need is more meaningful than time to defibrillation.

Time of First CPR Attempts

The time of first CPR attempts (ie, chest compressions or defibrillation attempts) should be recorded both for bystander-initiated CPR and CPR initiated by EMS personnel/healthcare providers.

Time of First Defibrillation Attempt If Shockable Rhythm

This time should be recorded in real time when the first shock is delivered. The best way to obtain this information is through an AED or conventional defibrillator with automated event documentation. These devices provide precise details about initial rhythm, times, and responses of heart rhythm to therapy. In the hospital, the time interval from collapse/arrest to first defibrillation attempt may be the most important process indicator of effective response when VF is the initial cardiac arrest rhythm.

Recommended Supplementary Time Events to Be Recorded

These time points are useful for internal quality assurance or research but are not deemed core time elements. They are either not considered as important in assessing process or outcome or problems are inherent in their accuracy and reproducibility.

Time When First Emergency Response Vehicle Is Mobile

This is the time when the emergency response vehicle begins to move. The interval between the time that the call was received and the time that the vehicle began to move usually is documented precisely and is important for quality assurance (eg, prolonged intervals may be the result of prolonged call processing or slowness of ambulance personnel).

Time When Vehicle Stops

This is the time when the emergency response vehicle stops moving at a location as close as possible to the patient. This time is documented precisely and is an important quality assurance measure.

Time of Return of Spontaneous Circulation

This time marks the return of any palpable pulse in the absence of ongoing chest compressions. If invasive intraarterial blood pressure is being monitored, then systolic blood pressure >60 mm Hg can be used as the surrogate for a palpable pulse.

Time When Vascular Access Achieved and Time When Medications Given

The value of intravascular or tracheal medications used in cardiac resuscitation has yet to be determined^{15,21}; nevertheless, their effectiveness may be time dependent. For this reason, the time of medication administration may be useful.

Time When CPR Stopped/Death

Numerous psychological and situational factors influence the time at which CPR is stopped, and this time point often

is imprecise. Nevertheless, this information may be useful (eg, for developing guidelines on when to stop CPR). Duration of CPR is an important quality assurance issue (eg, provision of CPR for 1 to 2 hours may be inappropriate) and is a supplementary data item.

Previously Recommended Time Points That Are No Longer Recommended

Departure from Scene and Arrival at Emergency Department

This time point was deleted because it differs greatly among EMS systems, especially when distances from the scene to the emergency department vary greatly.

Time When Tracheal Intubation Achieved

The importance of this time is unclear, especially in light of increasing evidence that effective airway control and adequate ventilation of the lungs are more important than the specific intervention of tracheal intubation.

Time When Arrest Confirmed, Time of End of ROSC, and Time of Awakening

These time points were deleted because of their imprecise definitions and the practical difficulties encountered in documenting the times accurately.

Time of Arrival at Patient's Side

This time point also was deleted because of imprecise definition and practical difficulties documenting this time accurately, especially in hospitals, because team members arrive at different times.

Potential Problems and Solutions for Reporting Times

The accurate recording of resuscitation times is difficult because of the psychological stress and intensive work generated during resuscitation attempts and because clock accuracy is unreliable. Despite these problems, quality assurance and medicolegal requirements make such documentation a high priority. Well-constructed forms for reporting cardiac arrest and CPR can and should facilitate good record keeping.

Postresuscitation Phase

The original Utstein reporting templates for both out-of-hospital and in-hospital cardiac arrest include factors up until ROSC and thereafter jump to outcome measurements (ie, died in the hospital, was discharged alive, status of functional outcome) without designating specific postresuscitation factors during the in-hospital phase after ROSC. At the time this was logical because information on postresuscitation factors that affect outcome was limited.

It is now known that several postresuscitation variables influence outcome dramatically. Two randomized controlled studies of adults with out-of-hospital VF cardiac arrest report a significant improvement in outcome when hypothermia was induced after ROSC.^{22,23} Two other studies reported significant differences between hospitals in the survival of patients admitted after prehospital cardiac arrest. These differences were not explained by

prehospital factors.^{24,25} In addition to body temperature, a negative association was found between survival and each of the following: high blood glucose levels, seizure activity, and low pH.²⁴ These observational studies do not prove that treatment of these factors improves outcome, but they should provoke further research. Cardiovascular and respiratory dysfunction also are present to a variable degree during the first 24 hours after resuscitation, and interhospital variations in monitoring and treatment are likely to influence outcomes. More important, regional and local differences in approaches to limitation and withdrawal of technological support can dramatically influence the length of stay and survival.²⁵

In many communities, the difficulty of linking prehospital and hospital data is insurmountable. As a minimum, the experts agree that whether hypothermia was induced should be included in reports as a core element. Additional desirable postresuscitation factors such as body temperature (both hyperthermia and hypothermia), blood glucose values, seizure activity, and some hemodynamic and ventilatory/blood gas variables may be important supplementary elements for specific research reports.

Data Access and Management

The collection and collation of sudden cardiac arrest registry data pose several challenges for EMS providers and researchers. A person who experiences a sudden out-of-hospital cardiac arrest often is treated by lay rescuers, public safety responders, or EMS responders, as well as a range of healthcare providers in the emergency department, coronary care or intensive care unit, and general ward. Information about the structure, process, and outcome associated with each of these settings may be collected sequentially by a single individual or multiple individuals representing each setting. If the latter occurs, then it may be difficult to track the care provided for each patient.

Collation of cardiac arrest data for entry into a registry may be done locally, regionally, nationally, or internationally. A significant advantage of collating data in a regional or larger database is that doing so enables individual clinicians or EMS systems to compare their own patient populations, interventions, and outcomes with those of other systems. This then enables clinicians and EMS providers to identify opportunities to improve quality of care and ascertain whether resuscitation is being provided according to evidence-based guidelines.

The task force was aware that some investigators are reluctant to contribute data to a central registry. Their reasons include concerns about ownership, data security, confidentiality, and resources. These concerns can be resolved by collaboration and the open exchange of ideas. The application of new computer technology can ensure data security through the use of firewalls, encrypted passwords, and deidentifying individual patient records. The concerns about data ownership and intellectual/academic recognition could be addressed through written understandings with each of the key stakeholders.

In most jurisdictions, local privacy laws and provisions will govern the collection of cardiac arrest data for a registry. The task force recommends that sites participating in a registry seek review and approval from their institutional review board or ethics committee to ensure compliance with local standards for health data registries and informed consent.

The task force also considered data accuracy defined by the ability of a measurement to match the true value of the quantity being measured. This is a particular challenge with sudden cardiac arrest data for several reasons: Intervals often are underestimated or reported in convenient numbers, such as even numbers or multiples of 5; patient factors are difficult to verify because most patients are not available for interview after the event; care processes are difficult to verify; and long-term outcomes, such as post-discharge status, often are difficult to obtain. Where resources are available, data should be reabstracted at each site to enable assessment of the quality of the registry data.

As with data accuracy, the reliability or similarity of results among different observations, experiments, or trials also presents a challenge for registries. Cardiac arrest data elements tend to be underreported and incomplete.²⁶ Every effort should be made to ensure completeness of data. Restricting data elements to the recommended core items listed in the present statement will facilitate completeness.

Data Linkage

Data linkage involves the collation of records for an individual from various sources into one cumulative file.²⁷ Increasing globalization, conversion from a paper-based to an electronic-based health record system, and development of increasingly user-friendly linkage software have strengthened opportunities for data linkage and global data integration.

Record linkage is a vital component of local, regional, national, and even international data and health information management.^{28,29} Through linkage it becomes possible to track fragmented health information, input missing or inconsistent data, and measure short- and long-term health outcomes while adjusting for covariate risk, demographics, and potentially confounding variables in health service evaluation and research. Linkage can help tie together structure, process, and outcome variables within large registries, which will facilitate benchmarking of cardiac resuscitation activities. For example, dispatch, prehospital, first responder, ambulance, defibrillator device, hospital, and death registry data could be incorporated into a single database. Linked registry data can support continual quality improvement within hospitals, communities, health networks, and countries. By virtue of its population-based approach, data linkage helps avoid selection bias. Because data are collected without any known purpose or outcome a priori, reporting and recall biases are minimized.

Concerns about privacy, confidentiality, and information security have led many countries to enact strict legislation to protect data (eg, in the United States, the Health Insurance Portability and Accountability Act). This sort of legislation has constrained the ability to link large registries across and within national boundaries.²⁹ Conflict between the rights of the individual to protect information about himself or herself

and the responsibility of health services to improve healthcare delivery makes record linkage difficult.

Implementation

Global information sharing is difficult to implement. The scientific community needs to address state/provincial, regional, and national regulations that limit sharing of data related to individual patient outcomes after resuscitation. Barriers exist among

- Prehospital and in-hospital systems to determine specific patient outcomes at hospital discharge
- Data repositories to determine specific patient outcomes at 30 days, 6 months, and 1 year
- Registries to enable sharing of minimally identified data into an international resuscitation database

The reports generated from existing registries should conform to the Utstein template, enabling communication and comparison among registries.

The importance of collecting and sharing resuscitation data must be made clear to the public and to relevant regulators. Protecting patient confidentiality is paramount, but with the appropriate safeguards, it should still be possible for key organizations to share data. Examples include public health databases and population-specific registries such as those established for cancer. Cardiac arrest registries should be no different. Patient advocates, national resuscitation organizations, and ILCOR should actively engage the appropriate legislative and regulatory bodies to facilitate the development and sharing of registry information.

Summary

Outcome after cardiac arrest and CPR is dependent on critical interventions, particularly early defibrillation, effective chest compressions, and advanced life support. Utstein-style definitions and reporting templates have been used extensively in published studies of cardiac arrest, which has led to greater understanding of the elements of resuscitation practice and progress toward international consensus on science and resuscitation guidelines.⁷ Despite the development of Utstein templates to standardize research reports of cardiac arrest, international registries have yet to be developed.

In April 2002, an ILCOR task force met in Melbourne, Australia, to review worldwide experience with the Utstein definitions and reporting templates. The task force revised the core reporting template and definitions by consensus. Care was taken to build on previous definitions, changing data elements and operational definitions only on the basis of published data and experience derived from those registries that have used Utstein-style reporting. Attention was focused on decreasing the complexity of the existing templates and addressing logistical difficulties in collecting specific core and supplementary (ie, essential and desirable) data elements recommended by previous Utstein consensus conferences.¹⁻³ Inconsistencies in terminology between in-hospital and out-of-hospital Utstein templates also were addressed.

The task force produced a reporting tool for essential data that can be used for both quality improvement (registries) and research reports and that should be applicable to both adults and children. The revised and simplified template includes practical and succinct operational definitions. It is anticipated that the revised template will enable better and more accurate completion of all reports of cardiac arrest and resuscitation attempts. Problems with data definition, collection, linkage, confidentiality, management, and registry implementation are acknowledged, and potential solutions were offered. Uniform collection and tracking of registry data should enable better

continuous quality improvement within every hospital, EMS system, and community.

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In 1991, the authors of the original Utstein uniform reporting guidelines wrote, "...certain features of the Utstein guidelines will need to be revised and supplemented." The recommendations in this document emanate directly from work published in previous Utstein consensus conferences and ILCOR advisory statements. Specific recognition is due Richard Cummins, Douglas Chamberlain, and Peter Safar, who encouraged the world to cooperate to understand the pathophysiology of cardiac arrest and resuscitation. We dedicate this update to their efforts and to the many scientists who strive to make their dream a reality.

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非医療従事者による自動体外式除細動器（AED）の使用のあり方検討会 報告書

平成16年7月1日

【照会先】

厚生労働省医政局指導課 TEL 03-5253-1111

担当：宮本、中田（2554、2559）

第1 はじめに

1 病院外の心停止の発生と医療の状況

(1) 我が国の救急医療対策と心原性心停止の発生件数

- 我が国の救急医療対策については、これまで、主として外来医療を担う初期、入院が必要な重症患者に対応した二次及び多発外傷等の重篤患者を受け持つ三次の段階を追った救急医療施設と、救急医療情報センターからなる救急医療体制の計画的かつ体系的な整備を推進してきた。また、平成3年に救急救命士制度を発足させるなど病院前救護体制の充実にも努めてきたところである。
- 病院外の心停止の発生については、救急搬送活動を通じて収集された1990年代後半を中心とした一部地域のデータの解析によると、年間の発生頻度は人口10万人当たり34～49件で、このうち心原性心停止の発生率は18～26件であった¹⁾。このことから、病院外の心原性心停止の件数は、年間2～3万件程度と推定される。
- 心疾患による死亡者数は平成13年148,292人、平成14年152,518人、平成15年163,000人²⁾と、増加する傾向にある。今後も、高齢化の進展により心筋梗塞等の心疾患が増加する見通しである。

(2) 緊急の除細動を必要とする不整脈の原因となる疾患

- 病院到着時に心停止状態であった患者の剖検の報告³⁾や、東京都監察医務院が行った剖検の報告⁴⁾によると、心原性心停止をもたらす具体的疾患としては、虚血性心疾患を中心とし、心筋症、心筋炎、大動脈解離などが含まれる。
- 虚血性心疾患によって突然死をきたす病態としては、心室細動による不整脈死、ポンプ機能の不全、心筋の破裂などがあり、それぞれの頻度は十分に明らかとなっていないものの、虚血性心疾患を原因とした心室細動及び無脈性心室頻拍の頻度は相当程度高いものと考えられている。
- 従って緊急の電氣的除細動を必要とする心室細動及び無脈性心室頻拍の原因となる具体的疾患としては、虚血性心疾患を中心として、その他、心筋症など、これらの不整脈を生じる疾患が含まれるものと考えられている。

(3) 電氣的除細動の効果

- 心臓は、刺激の伝達と心臓の収縮が秩序をもって規則的に起こることで、全身へ血液を流すという機能を果たしている。このため、刺激の発生と伝達が不調になると、心臓の拍動と血液の流れも影響を受けることがある。このうち、心室細動は、心室のいろいろな部分が無秩序に興奮し、その結果、規則的な心室の動きがなくなってしまう状態であり、これによって全身の血液の流れが止まるものをいう。また、無脈性心室頻拍は、心室で多くの刺激が規則的に生じる心室頻拍のうち、頻度が多すぎることによって心室の収縮機能が十分果たせず、全身の血液の流れが止まってしまうものをいう。
- 電氣的除細動は、心臓に一過性の高エネルギーの電流を流し、この電気ショックによって心臓の異常な興奮を抑制して、正常な刺激の発生と心臓の動きを取り戻す治療法であり、心室細動や無脈性心室頻拍といった生命に関わる重大な不整脈が生じた際には、直ちに行わなければならない。
- 心電図が心室細動又は無脈性心室頻拍の波形を示す場合に救命が成功する可能性は、発症から基本的心肺蘇生処置が開始されるまでの時間と、発症から電氣的除細動が行われるまでの時間によってほぼ規定され、より迅速に実施された場合ほど救命率は良好であることが示されている。
- 一方で、救急搬送の充実により、119番通報から救急隊員の現場到着までに要する時間は平

均 6.3 分程度 (平成 14 年) となつてゐるが、救急隊員の到着までの間に現場に居合わせた者 (バイスタンダー) 等によつて電氣的除細動が速やかになされれば、救命にとって有効となることが期待される。

2 自動体外式除細動器を用いた除細動の医行為該当性

- 電氣的除細動に用いられる医療機器 (除細動器) は、1947 年、米国において臨床で使用されて以来、約 60 年が経過している。この間、他の医療機器と同様に、小型で携帯性に富み、かつ、安全で操作性の高いものとして、自動体外式除細動器 (AED (Automated External Defibrillators)。なお、本報告書では、対象者に電極を貼付すれば、機器が心電図波形を自動的に解析し、電氣的除細動が必要かどうかを判断・表示し、必要な場合に限り使用者がボタンを押すことで通電が可能なるものをいうこととする。) が開発されている。除細動を行うべきでないと判断される場合には、使用者がボタンを押した場合でも、通電できないようあらかじめ設計されている。また、通電時に対象者に触れないようにすることなど、実施に際して必要となる注意事項についても、自動音声で使用者に警告するなど、安全に使用できるよう様々な配慮がされている。
- これまでの研究で、自動体外式除細動器を使用した場合の事後検証が行われており、電氣的除細動が緊急に必要なでなかつたにも関わらず電氣的除細動を目的として通電したという事例は無かつたことが示されている⁵²⁾。
- しかし、自動体外式除細動器を用いる場合でも、
 - ・ 対象者の意識及び呼吸の状態を確認すること
 - ・ 対象者にペースメーカーが埋め込まれていないか、貼付薬剤が使用されていないか等を確認すること
 - ・ 対象者の周囲に水などの伝導性の物質がないか確認すること

等は必要であり、これを怠れば、対象者の生命身体に危険を及ぼすだけでなく、使用者の生命身体に危険が及ぶ可能性がある。このようなことから、心停止者に対する自動体外式除細動器の使用については、医学的知識をもつて行うのでなければ傷病者の生命身体に危険を及ぼすおそれのある行為、いわゆる「医行為」に該当するものと考えられ、これまでは医師又は医師の指示を受けた看護師若しくは救急救命士がその専門的知識に基づき行うものとされ、これらの者以外の者 (以下「非医療従事者」と総称する。) の使用については、反復継続する意思をもつて行うことは認められていなかった。

(注) 医師でない者が医行為を反復継続する意思をもつて行えば、医師法 (昭和 23 年法律第 201 号) 第 17 条違反となり、刑事罰が科される。

- 一方で、救急救命士の業務拡大については、平成 14 年以降有識者による検討会で議論され、平成 15 年から平成 18 年にかけて、順次拡大が図られることとなつた。このうち、電氣的除細動については、平成 3 年に救急救命士制度が創設された当初から、医師の具体的指示の下で、除細動を実施することが認められていたが、医師の指示を受けるまでに時間が要することもあつたことから、追加講習の受講や、事後検証を的確に行うるメディカルコントロール体制の整備などを条件に平成 15 年 4 月より医師の包括的指示下での除細動の実施が認められている。

3 非医療従事者による自動体外式除細動器の使用に関するこれまでの政府の対応

- 平成 15 年の構造改革特区提案に際し、心停止者に対し、救急隊員の到着までの間に現場に居合わせた者 (バイスタンダー) が電氣的除細動を速やかに行うことがより有効であるとの観点から、非医療従事者による自動体外式除細動器の使用を認めるべきとの提案がなされた。その際、自動体外式除細動器については、米国や英国などの一部の諸国で、講習を受講した一般市民にもその使用が普及しており、その安全性・信頼性について、概ね評価が確立していることが指摘されたところである。
- 同年 9 月、政府は、構造改革特別区域推進本部の決定として、少なくとも次の 4 つの条件を満たす場合には、非医療従事者が自動体外式除細動器を用いても、医師法違反とならないものとするの方針を明らかにしたところである。
 - (1) 医師等を探す努力をしても見つからない等、医師等による速やかな対応を得ることが困難であること
 - (2) 使用者が、対象者の意識、呼吸がないことを確認していること
 - (3) 使用者が、自動体外式除細動器の使用に必要な講習を受けていること
 - (4) 使用される自動体外式除細動器が医療用具として薬事法上の承認を得ていること

- 当検討会は、このような状況を踏まえ設置され、救急蘇生の観点からみた非医療従事者による自動体外式除細動器の使用条件のあり方、自動体外式除細動器の使用に係る講習などの必要な環境整備や、自動体外式除細動器に関する国民の理解の促進及び普及啓発を図る方策等について検討し、その考え方をとりまとめたものである。

第2 非医療従事者が自動体外式除細動器を使用する条件についての考え方

1 非医療従事者の参画による救命の体制強化

- 前述のとおり、救急医療体制や病院前救護体制は、これまで、関係者の努力により充実・強化が図られてきている。これをより一層推進するためには、救急隊員の現場到着を早める努力と並んで、「救命の連鎖」をその出発点において、より多くの人々の参画により強化することが必要である。一般市民を含めた幅広い非医療従事者が参画し、救急救命士を始め救急搬送に従事する者に適切に引き継ぐことにより、「時間の壁」を乗り越えることに資するものであるべきである。

2 傷病者の安全の確保

- 時間を争う救急蘇生の局面にあっても、何にもまして、傷病者の安全が優先されなければならないことは論をまたない。非医療従事者が自動体外式除細動器を使用法に則り適正に使用する場合の救命率向上に資するものとし、使用に伴う傷病者の不利益をゼロに近づけるとの方向にかなうものであるべきである。

3 使用者の安心の確保による積極的対応

- 救命の現場に居合わせた一般市民を始めとする非医療従事者が、安心感・自信をもって、積極的に救命に取り組むことを促すようにするものであるべきである。
- 上記の4条件は、業務の内容や活動領域の性格から一定の頻度で心停止者に対し応急の対応を行うことがあらかじめ想定される者が自動体外式除細動器を用いたときに医師法第17条との関係で示されたものである。一方、救命の現場に居合わせた一般市民が自動体外式除細動器を用いることは一般的に反復継続性が認められず、医師法違反にはならないものと考えられる。医師法違反の問題に限らず、刑事・民事の責任についても、人命救助の観点からやむを得ず行った場合には、関係法令の規定に照らし、免責されるべきであろう。
- 当検討会が示す条件は「法違反に問われない」、「損害賠償責任を問われない」という、言わば消極的な安心感を与えるものにとどまらず、医学的知識を含め救命についての理解に立って、自信を持って救命に積極的に取り組むことを促すものであるべきである。

第3 非医療従事者の自動体外式除細動器の使用に当たっての条件整備

- 上記第2の考え方に則し、当検討会として、政府の構造改革特別区域本部決定の4条件を改めて検討したところ、概ね妥当であり、これらに比肩するまとまりをもった条件で追加すべきものはないとの結論に至った。
- その上で、これら4条件の具体化に向け検討したところ、それぞれ以下のようなものとするのが適当との結論を得た。なお、4条件の順番は重要性の順を示すものでなく、自動体外式除細動器の使用に当たっての時間的な先後を示すものでないことに関係者は留意すべきである。

1 医師等による速やかな対応を得ることが困難であることについて

- 医師等による速やかな対応を得ることが困難なときにあっては、心停止者に対する処置が緊急を要することを考慮し、より迅速に除細動が開始されるよう努めることが適切である。

2 対象者の意識と呼吸がないことの確認について

- 自動体外式除細動器は、心停止を伴う不整脈について、除細動が必要である場合を判別する機能を備えており、心停止を伴わず、対象者の意識がある状況で誤って通電する可能性は低いと考えられるが、関連する基本的心肺蘇生処置の実施を含め、除細動の実施には、呼びかけや身体の接触に反応が無いこと、呼吸がないことを確認することが前提として必要である。
- なお、これらの確認のための具体的方法については、3(1)の講習の内容に含まれることが必要である。

3 自動体外式除細動器の使用に関する講習について

- 心停止者が救命される可能性を向上させるためには、迅速な基本的心肺蘇生処置と、迅速な電氣的除細動が、それぞれ有効であることが明らかとなっている。また、自動体外式除細動器の使用に当たって、意識や呼吸の有無を的確に判断する技能を身につけることが必要である。これらのことから、自動体外式除細動器の使用に関する講習において、既に基本的心肺蘇生処置に習熟していると考えられるなどの場合を除き、基本的心肺蘇生処置を含むことが適切と考えられる。
- ただし、基本的心肺蘇生処置は、いったん習得してもその技能の維持が必ずしも容易ではないなど、課題があることが指摘されている。また、基本的心肺蘇生処置を伴わずに、電氣的除細動だけを行った場合にも、特に発症直後では優れた効果が認められている。そのため、自動体外式除細動器の使用の普及に力点を置き、救命への国民の参加の意欲を喚起することに資するものとすべきとの考え方にも留意すべきである。
- 当検討会としては、これらを総合的に勘案し、講習について次のように具体化を図った。その際、この講習は、第2の3に示したとおり、救命の現場に居合わせ自動体外式除細動器を使用する一般市民については、医師法との関係で義務的な条件とはならないものの、自信を持って積極的に救命に取り組むためのものであるとの認識が、関係者に共有される必要があるものとする。

(1) 講習の内容及び時間数

- 病院外での基本的心肺蘇生処置や電氣的除細動の実施を起点に、搬送途上における処置を経て、医療機関での治療までといった救命のために行われる「救命の連鎖」の一環を非医療従事者が担うことが期待されるものであることから、講習では、非医療従事者に、救急搬送を経て救急医療への実施という一連の流れと、その中における行為者自らの位置付けを理解してもらうことが必要である。さらに、早期の電氣的除細動の必要性と効果、自動体外式除細動器の安全な操作法について講習を通じて理解してもらうことが必要である。
- 除細動の準備ができるまでの間や、心静止状態（心停止のうち、心筋の収縮が全くなく、心電図でも何ら波形が見られない状態）にあつて自動体外式除細動器の自動解析機能がその心停止者について除細動の適応がないと判定した場合など、心臓マッサージ等の基本的心肺蘇生処置を行うことが期待される場合があることや、意識や呼吸の有無を的確に判断する技能を身につける点から、講習では、心臓マッサージ等の救命処置の基本を理解してもらうことが必要である。
- また、講習の実施に当たり、効果的に知識・技能の習得がなされるよう、講義にあわせ、機器等を用いた実習を適宜組み合わせる必要がある。
- これらの内容を含む講習については、受講する非医療従事者に過度の負担を生じさせることなく、より多くの国民に自動体外式除細動器の使用を普及させる観点を加味すれば、講師の技量や、講師に対する生徒数、実習に用いる自動体外式除細動器の数などの状況により変動するものの、概ね3時間程度で必要な内容を盛り込み実施可能と考えられ、その時間数の中で、概ね別紙程度のもので履修することが適当である。

(2) 講師

- 関連する基本的心肺蘇生処置及び自動体外式除細動器の使用に関する十分な知識・経験を有する有資格者が講師を務めることが望ましい。
- 上記の者の他、地方公共団体の消防担当部局や公的な団体が実施する一定の講習プログラムを終了した非医療従事者が、一般市民を対象とした基本的心肺蘇生処置の指導員となり、これまでも講習のすそ野を広げることに貢献してきている実績に鑑み、自動体外式除細動器の使用に関する教授法を含む指導教育プログラムを終了した者も講師として活用すべきである。
- このため、自動体外式除細動器を始めとする救急医療の実情を熟知するとともに、各種の救急医療関係の講習の実績を有している公的な団体において、関係学会等の協力を得て、講師養成のための指導教育プログラムを作成し、その普及を図ることが適当である。

(3) 多様な実施主体を通じての講習の質の確保

- 自動体外式除細動器の使用に関する理解が国民各層に幅広く行き渡る必要があることから、職域や教育現場で実施される講習も含め、多様な実施主体による対象者の特性を踏まえた多様な講習が実施されることが期待される。
- 救命の質と除細動を受ける者の安心を確保するために、講習の内容、講師、用いる教材・機材等については、上記(2)の公的な団体が、講習を実施する主体からの相談に応じ、情報提供や技術的助言を行うことを通じて、その質の確保を図ることが考えられる。