

What Must be Done to Spread the Use of AED?

– The Japanese Example –

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It is said that more than 40,000 people die every year in Japan due to acute myocardial infarctionⁱ, about five times more than those who die from traffic accidentsⁱⁱ. It is also said that more than 20,000 people die every year in Japan due to arrhythmia such as ventricular fibrillationⁱⁱⁱ. When five minutes pass after ventricular fibrillation is generated and the heart fails to perform its function, the probability of the patient's death is beyond 50%. Even if the patient does not die, it is very likely that a fatal obstacle will occur in the brain as an aftereffect. When ventricular fibrillation is generated outside the hospital and an ambulance is called, it would take the ambulance about seven minutes on average (national average) to arrive. As such, the patient may have only a slim chance of survival.

An automated external defibrillator, abbreviated as "AED," is a medical equipment that gets rid of ventricular fibrillation in a person by applying electronic shock to the person, and that revives the function of the heart. An AED installed in a person who experiences ventricular fibrillation can save the person's life. AED raises the possibility of the patient's resuscitation. This explains why the use of AED has spread in many countries.

The purpose of this report is twofold: (1) to find the answer to the question "What must be done to spread the use of AED?" by presenting the Japanese example; and (2) to give people, such as policymakers or researchers who are troubled by the non-practical use of AED and by the fact that its use in the country has hardly spread, the appropriate

ⁱ There are many cases of ventricular fibrillation as an initial symptom of acute myocardial infarction.

ⁱⁱ "Death toll according to the main cause of death in Japan", Statistics Bureau of Ministry internal Affairs and Communications, <http://www.stat.go.jp/data/nihon/g4821.htm>

ⁱⁱⁱ "Death toll according to the main cause of death in Japan", Statistics Bureau of Ministry internal Affairs and Communications, <http://www.stat.go.jp/data/nihon/g4821.htm>

advice and directions. I am convinced that the use of AED can save the lives of many people.

This article is organized as follows. First, I will examine the importance of enacting pertinent laws and ordinances. Second, I will discuss the necessity of performing an epidemiologic investigation and of analyzing the economic effect of AED use. Finally, I will consider the improvement of AED's accessibility.

1. The enactment of pertinent laws and ordinances is necessary to spread the use of AED.

What must be done to spread the use of AED? Legitimate support is necessary. Pertinent laws and ordinances must be enacted to clarify who are legally allowed to use AED and to exempt people who help patients using AED from legal accountability if the patient's condition worsens on account of his/her AED use.

AED was invented in 1947. I think that what explains why AED has not been used widely for public-access defibrillation (PAD) in spite of its improved safety and operation is its non-legal maintenance.

It was the Cardiac Arrest Survival Act (HR 2498) that triggered the rapid spread of AED in the United States. After former U.S. president Bill Clinton signed the Cardiac Arrest Survival Act into law to save the lives of 20,000 people who were expected to die on account of ventricular fibrillation every year, AED has been installed public places in the U.S., such as in federal-government buildings and commercial airplanes. Former U.S. president George W. Bush also supported the legislation. On account of its administrative promotion, the installation of AEDs is spreading in the U.S. Besides the Cardiac Arrest Survival Act, each U.S. state has enacted a law concerning PAD and supports the use of AED by non-physicians.

The Cardiac Arrest Survival Act exempts non-physicians who help patients using AED from legal accountability but does not allow the use of AED, for safety reasons. The Act, also called "Good Samaritan Law,"^{iv} exempts a person who attempts to save the life of

^{iv} The Good Samaritan Law was based on the Parable of the Good Samaritan in the Bible: "A man was going down from Jerusalem to Jericho when he fell into the hands of robbers. They stripped him of his clothes, beat him, and went away, leaving him half dead. A priest happened to be going down the same road, and when he saw the man, he passed by on the other side. So too, a Levite, when he came to the place and saw him, passed by on the other side. But a Samaritan, as he traveled, came where the man was; and when he

a person suffering from cardiac arrest through the use of AED from legal accountability even if such assistance eventually worsens the patient's condition. In other words, if an AED is used by a non-doctor, such as according to its voice guide, even if the patient eventually dies, the non-doctor who used it on the patient will have no legal accountability.

If there were no such law in existence, if a person collapses and becomes unconscious, does a doctor who happens to pass by not have the obligation to help the patient even if the patient does not ask for help? I think that this question is legally contentious. It is clear that the doctor will violate the medical law if he refuses to help the patient without a valid reason, but if the patient is not asking for help, should the doctor help him/her? What if the patient who has not asked for help dies while the doctor is giving him/her first aid? Again, this question is legally contentious. I am not aware of the boundaries of the responsibilities of doctors, but I know that a non-doctor will find it hard to administer first aid to a patient even if he/she is freed from legal accountability should the patient eventually die. Even if a non-doctor has a good heart and wants to help a person experiencing cardiac arrest, he cannot offer much help in such situation. This is one of the reasons that the use of AED has not spread. The Cardiac Arrest Survival Act, however, has addressed this problem.

In the case of Japan, a legitimate point regarding the aforementioned issue is slightly different from the American example. Japan has an act that is like the Good Samaritan Law: Civil Code Article 698^y. It is written therein that "one who administers help to another person in an emergency situation, without having the duty to do so, shall be exempt from legal accountability in the event of the death of the person who was helped, or of damage to the latter's property or honor, unless the death of the person who was helped or the damage to such person's property or honor was intentionally done or was the result of gross negligence on the part of the person who helped". Therefore, there is no argument about the legal accountability of non-physicians who use AED in Japan. On the other hand, there is an argument regarding whether AED use violates the Medical Act in Japan, where it is written that "the doctor is the only one who can practice medicine".

saw him, he took pity on him. He went to him and bandaged his wounds, pouring on them oil and wine. Then he put the man on his own donkey, took him to an inn, and took care of him."(Luke 10:31-34, NIV)

^y However, there are opinions to deny the similarity of Civil Code Article 698 and the Good Samaritan Law.

In other words, the decision that non-physicians have to make when they encounter a person who collapses due to ventricular fibrillation is whether to practice medicine or not to. According to the precedent of Medical Act^{vi}, which defined “the practice of medicine,” the practice of medicine has two requirements: it requires medical knowledge, and it needs to generate income through repetition. This issue can be summarized into the following three points:

- (1) Are the medical judgment and technology of a doctor necessary for AED use? Further, is AED use by a non-doctor likely to harm the patient?
- (2) Is the use of an AED to help a person a for-profit activity?
- (3) The act of helping a person through the use of an AED is repeated (repetition and continuation).

To address this problem, the Ministry of Health, Labor, and Welfare arranged a “Council to Consider the Use of AED by Non-physicians”, and to examine the problem of the law about the AED use of non-physicians and about the issue of AED’s safety from different angles. After four conferences, the council submitted a report where it was indicated that non-physicians are legally allowed to use AED. The following is an excerpt of the report^{vii} that was submitted by the council:

The external defibrillator device has been used in the USA since 1947. Its name was changed into AED after it was made portable through miniaturization, like other medical equipment. AED is easy to operate and is very safe. It automatically analyzes an electrocardiogram wave pattern by affixing an electrode to a person, and it indicates if cardioversion is needed. Electricity is then applied only when the user pushes the button. When a user, however, pushed the button when it was adjudged by the AED that defibrillation should not be performed, electricity will not be applied. In addition, the AED warns the user not to touch the person to whom electricity is being applied, via an automatic sound guide. Besides this, AED has many other features that ensure its safe use.

The above opinion shows that medical knowledge and technology are not necessary for AED use. This report also indicates that the use of AED by a non-physician to help a

^{vi} Sendai High Court, January 14 1953 judgment (Detective of High Court judgment flash 35 Clause 3)

^{vii} <http://www.mhlw.go.jp/shingi/2004/07/s0701-3.html>

person undergoing arrested ventricular fibrillation constitutes medical practice. The probability, however, of encountering a person who collapses due to ventricular fibrillation is very low. Furthermore, doubling this probability is still extremely low, and so it was concluded that when a non-doctor uses AED, it can be regarded as non-practice of medicine because there is no repetition nor continuation. After examining the report, the Medical Policy Division of the Ministry of Health, Labor, and Welfare announced 0701001 on July 1, 2004, which permits AED use by non-physicians. The aforementioned Japanese example answered Japan's oneself in a problem to relate to "who could use AED," and contributed to the installation of AEDs in public places and to AED use by non-physicians.

I am of the opinion that it is indispensable to enact laws and ordinances governing the use of AED and spreading such practice in the country. If a person who used AED to help a patient is sued by the patient who has been helped but whose condition became worse due to the use of AED on him/her, who will help patients even if AEDs have been installed in public places? I think that no one will do so. Therefore, there is a need to enact laws and ordinances that will not impose legal accountability on a person who helped a patient via AED use even if the patient's condition became worse due to the use of AED on him/her.

I think that laws and ordinances that indicate who can use AED should be enacted. There are European countries that do not have laws and ordinances about AED, especially laws and ordinances indicating who can use it^{viii}. In those countries that have a "Good Samaritan Law," the law does not impose legal accountability on a person who used AED to rescue another person who had an attack of ventricular fibrillation. However, I think AED use can be spread widely if it will be made clear who is allowed by the law to use AED rather than arguing regarding whether it is right for non-physicians to use AED in emergency situations. This is an important factor in spreading the use of AED. The absence of such laws and ordinances has stood in the way of the spread of AED use. Without the support of the legal system, AEDs will only be decorations in public places.

2. Medical inspection and economic analysis are necessary.

The legitimization of the spread of AED use depends on the results of the

^{viii} Sourced from "AED Use in Europe: Report on a Survey(2010)"

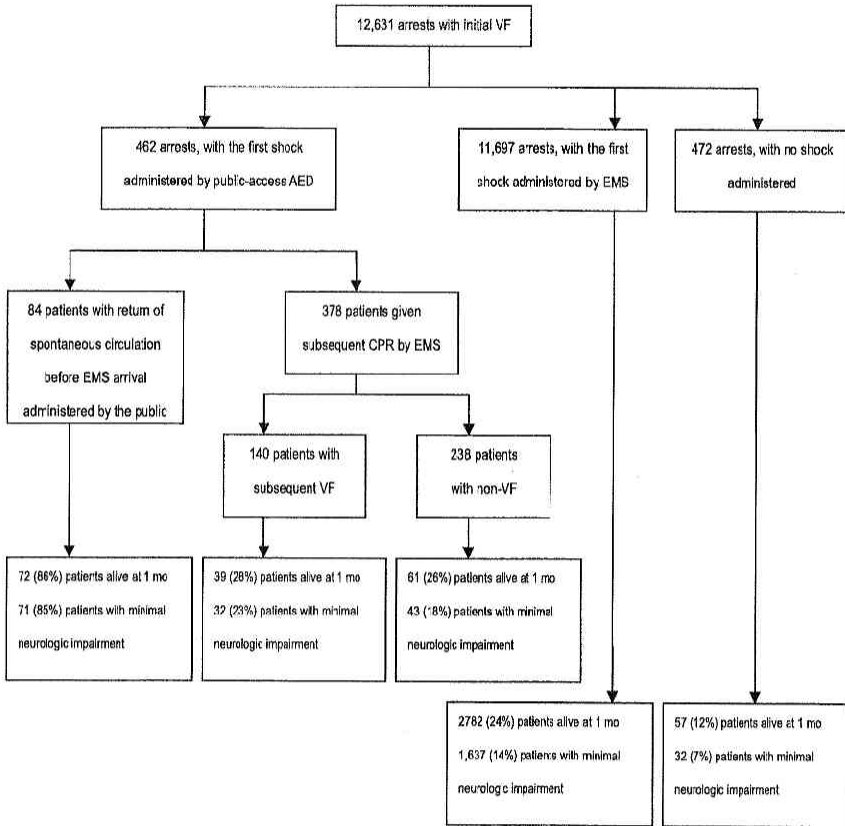
inspection of its medical effect (post-evaluation) and of its economic analysis (pre-evaluation). The inspection of its medical effect involves a comparison of the result of defibrillation performed by a non-physician with the use of an AED installed at a public place and that performed by a medical or emergency medical service (EMS) worker. If the result of the comparison shows that the defibrillation by the non-physician via the use of AED is more effective, the spread of AED use can obtain legitimacy. As for the economic analysis, it involves a judgment (before deciding whether to allow AED use or not to) of whether the policy of spreading the use of AED by allowing even non-physicians to use it will entail less expense than the alternative plan or will be advantageous. The spread of AED use does not have a driving force, and without medical inspection and economic analysis, few lives can be helped through the spread of AED use. Hardly any country has inspected the medical effect and economic validity of AED use.

There are countries that have inspected the medical effect of AED use through a national scheme, but the number of such countries can be counted using the fingers in one hand. When a search for documents regarding a nationwide inspection of the medical effect of AED use was conducted in Japan, Austria, and England, no such documents were found, and documents regarding a partial inspection are rare, having been found only in Germany. Other countries have no documents at all regarding even a partial inspection of the medical effect of AED use. Why are there no studies on the medical effect of AED use? I think that a study on the medical effect of AED use cannot be conducted because the pertinent data are not available. So why the lack of pertinent data? I think it is primarily because the first-aid system differs by area. In Europe, for instance, there are many countries that are decentralized. According to "AED Use in Europe: Report on a Survey", many Europeans answer "partly" when asked the question "To what extent has AED use by non-physicians been implemented?" As this answer indicates, there are cases where the ranges of people who are allowed by the law to use AED differ per area. When the environment of the user is different, as in a certain district, it is very difficult to gather unified data. Therefore, the inspection of the medical effect of AED use is impossible.

Fortunately, in Japan, the medical effect of AED use has been inspected, as reported by Kitamura et al. (2010). Having obtained the cooperation of the EMS workers in the country, they collected nationwide data from January 2005 to December 2007 and analyzed these statistically. They then explained why the effect of Public Access Defibrillation is superior. The effect of defibrillation via AED use by a non-physician is shown in Fig. 1. Defibrillation by non-physicians via AED use saved lives in 62% of the

cases, which is higher than the percentage of lives saved through defibrillation by EMS workers. In non-defibrillation cases, the difference is 74%(cf. Map 1).

Map 1. Number of lives saved by ventricular defibrillation in out-of-hospital cardiac arrest cases, as witnessed by bystanders



Source: Nationwide Public-Access Defibrillation in Japan (2010)

The inspection of such effect in England is similar. The life-saving rate of defibrillation via AED use is superior (cf. Table 1). Overall, the use of AEDs by non-physicians has a tenfold higher life-saving rate.

Table 1. Demographics and outcomes in the three groups of patients according to the responder and the location

Responder	No. (%)	Patients Shocked		Patients Not Shocked	
		No. (%)	Survival No. (%)	No. (%)	Survival No. (%)
A. Onsite AED	437 (28.6)	347 (79.4)	106 (30.5)	90 (20.6)	7 (7.8)
B. First responder outside the home	255 (16.7)	132 (51.8)	13 (9.8)	123 (48.2)	1 (0.8)
C. First responder at home	838 (54.8)	256 (30.5)	13 (5.1)	582 (69.5)	5 (0.9)
Whole group	1,530	735 (48.0)	132 (18.0)	795 (52.0)	13 (1.6)

Source: A National Scheme for Public-Access Defibrillation in England and Wales: Early Results (2008)

On another note, I think that the economic analysis of AED use is more important than the inspection of its medical effect. It can be argued that more lives can be saved through first-aid system maintenance than through the installation of AEDs in public places because the latter may have a superior advantage vs. the cost benefit or cost-effectiveness. If an economic-validity analysis of the matter will be performed beforehand, tax loss can be prevented, in particular. Moreover, by combining AED use with first-aid services, an effective first-aid environment can be created. I am disappointed, however, that no analysis of the economic validity of AED use has yet been conducted. I think that my article (2009), which analyzed the cost benefit of the introduction of AED use into Japan, is quite rare.

The economic analysis of AED use involves many difficulties or problems, such as whether AED use is a good substitute for EMS or should only supplement it. In addition, the most difficult task, the calculation of the value of human life, must be carried out so that the life-saving effect of AED use can be measured. There is also an ethical problem involved. I think, however, that it is necessary to analyze the life-saving effect of AED use from an economic perspective, in the same way that how the traffic light system can save lives via conversion must be evaluated to come up with an appropriate transport policy.

The analysis of the economic validity of AED use must also be accompanied by the following. First, for the alternative plan, an examination of EMS procedures for saving lives is necessary. Funds for reducing the time for an ambulance to arrive at the scene of emergency are also necessary to improve the EMS system. It is also necessary to investigate the synergy effect of AED use and people's willingness to pay (WTP) with regard to saving lives with the use of AED.

For reference purposes, allow me to introduce herein the results of some related

researches and of one specific and highly relevant trial. According to Inoue (2006), a 0.0088 increase in the first-aid transport per the population from 1990 to 2000 led to a 0.58 minutes increase in the time for an ambulance to arrive. This subsequently led to a 6.06 minutes increase in how fast the ambulance gets to the hospital. In addition, it is said that the ambulance spot arrival time decreased by about 0.26 minutes when average 16 of ambulances per the prefecture increased^{ix}.

I investigated the WTP in relation to AED use by employing the contingent valuation method (2007). I explained the advantages of the installation of an AED in a proximate place (e.g., security) to 309 people who were above 20 years of age who live in the Kanto area in Japan and examined their WTP. As a result, I obtained a median of 1,000 yen and a mean of 2,244 yen.

I wish to suggest herein a method of analyzing the effect of AED use. The survival rate of people who experience cardiac arrest due to ventricular fibrillation without defibrillation within five minutes of the arrest is under 50%. The value is seven minutes nationwide, in the mean time of the spot arrival of the ambulance. The mean times of the spot arrival of the ambulance in local areas, however, are different. If the mean time of the spot arrival of the ambulance in a local area is under five minutes, AED can be said to be a good substitute for first-aid service, and the allocation of revenue into the installation of AEDs in public places rather than into the expansion of the first-aid service will be helpful to the potential ventricular-fibrillation patients. It is also believed that the rate at which lives are saved will increase.

3. The improvement of the issue of accessibility of AEDs is required.

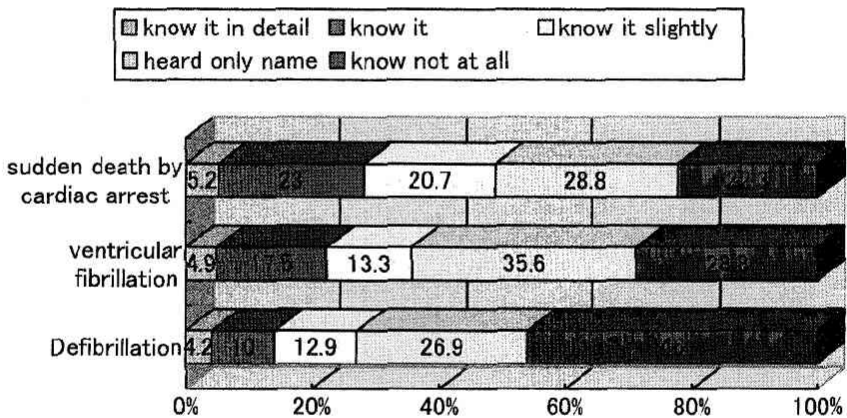
I look at the issue of accessibility from two perspectives. One is the problem of spatial access. It is in public places, such as in government buildings, that AEDs began to be installed in America. Europe also had three programs concerning AED settings: a community program, involving community responders such as police officers and firefighters; an onsite (including in-hospital) program, involving the trained staff at strategic public locations (e.g., airports, casinos, and locations within hospitals); and a home program, taking into consideration the fact that a great majority of out-of-hospital cardiac arrest cases occur at home (source: AED in Europe: Report on a Survey). The Japanese circumstances are the same. As regards the effect of the community program, however, the findings have given rise to a doubt regarding the helpfulness of the

^{ix} Inoue(2006), pp79.

installation of AEDs. According to a related American study, AEDs installed in police stations do not have very good life-saving effects. As such, it seems that there is a need to reexamine the effect of the installation of AEDs in public places. Besides, out-of-hospital cardiac-arrest cases usually occur in residential areas (about two-thirds of the cases). I thus believe that AEDs must instead be installed in residential areas as I believe that more lives can be saved that way, and as I believe that this will improve the AED access of the people who are going to help patients who will collapse due to ventricular fibrillation.

Another problem is psychological access. Even if legitimate maintenance of AEDs is performed and non-physicians are allowed to use AED, the effect of AED use based on the AED setting may be reduced to half if the life-saving performance of AED use is negative. I conducted a related survey among people with knowledge about AED and willingness to help patients in 2007, as follows (cf. Graph 1).

Graph 1. Question no. 1: Do you know the following?



The above graph shows that more than 70% of the people in Japan do not know defibrillation. This may be an obstacle to the accomplishment of PAD with AED. Only 22% of the people of Japan, however (70 of 309), answered “no” to question no. 2 (“Are you willing to operate an AED to save the life of a person who is suffering from cardiac arrest?”). Question no. 3 was “Why did you answer ‘no’ to question no. 2?” (cf. Table 2)

Table 2. Question no. 3: Why did you answer “no” to question no. 2?

Q3	Plural Replies	No.	%
1	Because I do not know first aid (medical treatments) very much, and I am not confident in that regard	59	84.3
2	Because it is scary to use an instrument I am not familiar with	42	60.0
3	Because I may be held accountable if something untoward happens to the patient	37	52.9
4	Because I think that if I do not help the patient, someone else (e.g., a station employee, a security guard, and EMS personnel) will do so	11	15.7
5	Because the person may have collapsed due to an epidemic, which will put me at risk of acquiring it if I help the person	2	2.9
6	Others	8	11.4
	Total	70	100.0

I think that it is good if 72% of the people are willing to operate an AED to save the life of a person suffering from cardiac arrest. However, I think there is room for improvement. As shown in Table 2, the reason that people answer “no” for question no.2 is because they do not know first aid medical treatment, they are too scared to use AED, and they want to avoid legal responsibility. If the administration and public groups join forces, access to psychology can be sufficiently improved. Concretely, such psychological problem can be addressed if the method of cardiopulmonary resuscitation will be spread and advertised to eliminate legal accountability from the use of AED. Fortunately, in the case of Japan, the use of AED is taught as an emergency measure in the driving schools, and many youths are thus familiar with AED use. I think that such a movement is desirable to improve the access to psychology and to boost life-saving rate through AED use.

4. Conclusion

AED use spread throughout Japan due to the enactment of the Medical Policy Division Code 0701001 of 2004, as mentioned earlier. AED use has been spreading widely in Japan since 2004. It can be cited that Japan is a developed nation when it comes to using AED. As for the factors that may contribute to the spread of AED, it is thought that administrative intention is indispensable along with maintenance of law and ordinance, and inspection of the medical effect of installed AEDs that I spoke of so far. That “the user must have received the necessary training for AED use” was made the first AED use qualification after the examination of AED use in 2003. The requirement that a non-physician must have had training in AED use before he/she can use AED, however,

disappeared as soon as the limit was set in July 2004. This may be a small but decisive factor. One who wants to use AED is not obligated to undergo training, so consequently, the use and installation of AED will increase (cf. Table 3).

It is certain that AED is the mechanism that is most effective for ventricular-fibrillation patients. What I have spoken of herein, however, must be considered for AED to be used most effectively. Countries that are deliberating the introduction of AED, or countries that have problems regarding scarce AED use, can utilize AED effectively if they refer to this article and to the example posed by the Japanese.

Table 3. Japanese trend of removal of the ban against AED use by non-physicians

2001.12	A case of AED use in an emergency situation by a cabin attendant in a plane does not conflict with the Medical Act.
2003.4	AED use by EMS personnel began (no need for doctor's instructions).
2003.6	St. John Ambulance Japan, The Japanese Circulation Society, and others suggested a "special first-aid and life-saving ward" where non-physicians were to be allowed to use AED.
2003.8	The Ministry of Health, Labor, and Welfare did not violate the Medical Act when it suggested the establishment of a special ward where non-physicians were to be allowed to use AED under the following conditions, and expressed the effect of such conditions on the acceptance of AED use by non-physicians: <ol style="list-style-type: none"> 1. when a doctor cannot be found, and when it is difficult to obtain prompt action from a doctor; 2. when the AED user confirms that the person on whom AED was applied was unconscious and was no longer breathing before the use of AED on him/her; 3. when the user has received the necessary training for AED use; and 4. when AED is to be used as a medical appliance, with approval from the Medical Instruments Act
2003.11	The Ministry of Health, Labor, and Welfare established "Council to Consider the Use of AED by Non-physicians" so that experts can examine the concrete terms of AED use and maintenance.
2003.11	First meeting
2004.1	Second meeting
2004.3	Third meeting
2004.5	Final meeting, where the bone character plan of the report was examined
2004.7	The Ministry of Health, Labor, and Welfare forwards a copy of the report to the local government. Permission was given for AED use by Non-physicians (no duty to acquire training)

Source: NPO AED Spread homepage, <http://www.aedjapan.com>

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