

There is no paper describing or outlining a comprehensive quality improvement plan. Many describe local program efforts. Kellerman 1993 and Davis 1998 report findings from QI reviews of two first responder AED programs and state that such reviews identified important performance and system issues for attention. A number of authors reported focused QA reviews of specific items, such as battery status and AED rhythm analysis (Cleland 1997, 1998 and 1999, MacDonald 2001). These all generally support the value of regular on-going QI to both identify problems prior to incidents and to evaluate system performance for cardiac arrest events.

**Preliminary draft/outline/bullet points of Guidelines revision:** Include points you think are important for inclusion by the person assigned to write this section. Use extra pages if necessary.

Annotated Bibliography

Citation Marker	Full Citation*
Calle 2001	<p>Calle, P. A., K. G. Monsieurs, et al. (2001). "Unreliable post event report from an automated external defibrillator." <u>Resuscitation</u> <b>50</b>(3): 357-61.</p> <p>Medical supervision of the use of automated external defibrillators (AEDs) is possible by the incorporation of a solid state memory system recording electrocardiography (ECG) tracings and information about the operation of the device. Since a post event report suggested inappropriate AED use erroneously, the information storage and printing processes of the Laerdal AED system were investigated. This analysis strongly suggests (yet unpredictable) incompatibilities between the software built in the solid state memory modules and the different components of the printing system. Although no problems were encountered during the resuscitation attempts, these findings may be clinically relevant because an unreliable post event report from a solid state memory module may lead to erroneous criticism of an AED user.</p> <p><i>Case report of incorrect data initially obtained when downloaded from AED. Three attempts yielded significantly different reports and would have led to incorrect critique of users.</i></p> <p><b>LOE 5 / Qual Good / Neutral (points out potential to be misled)</b></p>
Cleland 1997	<p>Cleland, M. J., J. P. Maloney, et al. (1997). "Relationship between battery capacity and the delivery of shocks in prehospital defibrillators." <u>Prehospital Disaster Med</u> <b>12</b>(2): 132-5.</p> <p>STUDY OBJECTIVE: Automatic external defibrillators (AED) have enabled the medical act of defibrillation to be performed in the community by a number of non-physician providers. However, these portable, battery-powered units are costly to maintain and service. This study examines the life of AED batteries and provides a battery replacement protocol. DESIGN: Prospective diagnostic testing of 191 field batteries to determine their ability to deliver shocks at 360 joule. SETTING: Ottawa General Hospital Paramedic Program. OUTCOMES: Using a battery analyzer, battery capacity and the number of shocks delivered were determined for each battery (at room temperature and in a controlled, refrigerated setting). In addition, the reliability of the testing method was assessed using the interclass correlation coefficient (ICC). RESULTS: High reliability of blinded technical assessment of the batteries was achieved (ICC = 0.85). A strong correlation between the battery's capacity and the number of shocks it can deliver was obtained. For example, a battery with a measured capacity of 75% is capable of delivering more than 30 consecutive 360 joule shocks. This compares to a battery with a capacity of 20%, which is capable of delivering only 12 consecutive 360 joule shocks. CONCLUSIONS: While manufacturers' recommendations on battery replacement always have been based on an assumed technical threshold, these recommendations are not based on individual battery performance. The system for testing batteries described in this paper, should provide significant cost savings and improve quality assurance within a prehospital AED program.</p> <p><i>This study reports that a method of AED battery capacity assessment with battery analyzer accurately predicts the number of shocks that a battery can deliver. The authors suggest this is a more reliable and perhaps more cost-effective method for battery replacement than the manufacturer's estimated lifespan. However, some batteries now have built in capacity meters and devices do self-check to assure adequate battery reserve left.</i></p> <p><b>LOE 6 / Qual Good / Support</b></p>
Cleland 1998	<p>Cleland, M. J., J. P. Maloney, et al. (1998). "Problems associated with the Z-fold region of defibrillation electrodes." <u>J Emerg Med</u> <b>16</b>(2): 157-61.</p> <p>To examine performance failures of automatic external defibrillator (AED) self-adhesive electrodes, a retrospective analysis of patient reports and electrodes was conducted in a suburban emergency medical service (EMS) system. In all cases, only records from out-of-hospital cardiac arrests (OHCA) were used if the EMS was activated and an AED was used. Electrode failures were assessed as follows: 1) EMS staff returned defibrillation electrodes when they were unable to resolve repeated "Check Electrode" messages, and 2) an audit of selected records was used to determine the frequency of electrode problems during calls. Of 302 OHCA calls during the study period, 22 (7%) resulted in returned electrodes. Defects (cracks or faults) in the internal conductor were present in 37 (86%) of the 43 returned electrodes; 2 (5%) possessed dehydrated conductive gel, and in 4 (9%) electrodes no faults could be identified. Of the 21 complete sets of defective electrodes, 16 (76%) had faults in both electrodes. Chart review revealed at least one "check electrode" message occurring in 21 (60%) of 35 OHCA reports. The electrode checks were present for a total of over 83</p>

	<p>min, representing 11% of the call times. Paramedics were required to change electrodes in 9 (26%) of the 35 cases, resolving the malfunction in all instances. Electrode malfunction appears to be a common prehospital problem; the conductor is responsible for the majority of electrode problems and is probably subjected to the most stress during storage and handling. More reliable, durable defibrillation electrodes are required for OHCA treatment. Other strategies for electrode storage and quality control are also discussed.</p> <p><i>This retrospective review of 302 cardiac arrests reports electrode malfunction occurred in 7%. Of these, 86% were cracks in the conductive part of the pad, the vast majority in the z-fold region. Authors make suggestions for reducing this rate, and stress importance of ongoing QA to assure electrode fitness.</i></p> <p><b>LOE 5 / Qual Good / Support</b></p>
Cleland 1999	<p>Cleland, M. J. and J. P. Maloney (1999). "Problem automated external defibrillator electrodes: are yours any better?" <u>J Emerg Med</u> <b>17</b>(6): 1065-6.</p> <p><i>This letter states that EMS agency found cracks or breaks in the conductive portion of electrode pads near connector to cable using fluoroscopy. This may affect detected impedance, ECG waveform interpretation and delivery of electric current. Brand not specified and if pad design changed may no longer be problem. However, still endorses value of routine checks of equipment and supplies.</i></p> <p><b>LOE 5 / Qual Fair / Support</b></p>
Colquhoun 2004	<p>Colquhoun, M., C. S. Davies, et al. (2004). "Public access defibrillation--designing a universal report form and database for a national programme." <u>Resuscitation</u> <b>61</b>(1): 49-54.</p> <p>We describe the design of a universal report form for use by lay-responders using an automated external defibrillator (AED) as part of a national programme for public access defibrillation (PAD). The form was designed initially because the Department of Health in England required detailed audit data about the national programme for public access defibrillation they initiated. At that time (1999) there was very little reported experience of public access defibrillation and none from the UK. The form evolved pragmatically as experience showed the wide range of situations under which lay-persons might use an AED, and also the information likely to be available that could be collected reliably. This report may help others who wish to audit schemes for PAD and facilitate the evolution of an internationally acceptable template for data collection.</p> <p><i>This paper describes an event report form for use by lay responders in a public access defibrillation program. It is proposed that use of form for auditing events will lead to improved performance and patient outcome and that its publication will facilitate evolution of an international template.</i></p> <p><b>LOE 8 / Qual Good / Support</b></p>
Davis 1998	<p>Davis, E. A. and V. N. Mosesso, Jr. (1998). "Performance of police first responders in utilizing automated external defibrillation on victims of sudden cardiac arrest." <u>Prehosp Emerg Care</u> <b>2</b>(2): 101-07.</p> <p>OBJECTIVE: Rates of resuscitation from cardiac arrest are directly tied to time to defibrillation. To maximize results, the first arriving care provider should be equipped and trained to defibrillate. This would include police in those systems where they serve this function; to date, no training program has been examined for effectiveness in this group. The purpose of this study was to evaluate a training program designed to train police first responders in the use of an automated external defibrillator (AED). METHODS: One hundred seventy police officers previously trained to the level of first responders underwent a four-hour course to teach incorporation of the AED in their practice. The evaluation of police performance was assessed by written tests prior to, immediately after, and six months post initial training. Actual field use was evaluated by using separate data collection forms filled out at the time of the resuscitation by both police and EMS providers. Each trip sheet was also reviewed. Cassette tapes from the AED were reviewed for continuous ECG tracings and audio recordings to validate and confirm the previous data. RESULTS: One hundred twenty-eight police cases were reviewed. The officers performed with few errors in AED operation, with the only problem areas being incorrect airway management and delay in performance of CPR to use the AED to reanalyze a nonshockable rhythm. These results were compared with those of the only two other studies examining the performance of first responders, which were EMTs and firefighters. The police results compared favorably with, and in some instances exceeded, those results. CONCLUSION: Police first responders trained in the use of AEDs performed at a level equivalent or superior to that in other reported studies. Future training strategies should stress proper integration of airway and CPR skills.</p> <p><i>Review of AED and responder reports allowed recognition of common errors in study of police use of AEDs. The most common errors were in airway management and inappropriate repetitive analyses after no shock advisory. Data review allowed authors to provide constructive feedback to individuals and address errors from system perspective.</i></p> <p><b>LOE 5 / Qual Good / Support</b></p>
Herlitz 1998	<p>Herlitz, J., A. Bang, et al. (1998). "Experience with the use of automated external defibrillators in out of hospital cardiac arrest." <u>Resuscitation</u> <b>37</b>(1): 3-7.</p> <p>AIM: To describe the sequences of arrhythmias, number of shocks delivered and the number of failures in a consecutive series of patients with out-of-hospital cardiac arrest attended by our emergency medical service (EMS) and in whom cardio-pulmonary resuscitation (CPR) was initiated and in whom automated external defibrillators (AEDs) were used. PATIENTS: All patients with out-of-hospital cardiac arrest attended by the EMS and in whom AEDs were used. Time for inclusion in the study: January 1st, 1987 to December 31st, 1992. RESULTS: In all there were 1781 out of</p>

	<p>hospital cardiac arrests during the study period. Among them AEDs were used in 383 cases (22%). The total number of interpreted rhythms delivered in these patients was 2719. Among all rhythm sequences coarse ventricular fibrillation (VF) was found on 375 occasions (14%); fine VF on 107 occasions (4%) and ventricular tachycardia (VT) on 12 occasions (0.4%). In ten cases with coarse VF (nine patients) the AED did not advise a shock (2.7%). In five of those nine patients a human error was interpreted as the explanation and in four there was a possible technical error. In these four patients defibrillation was delayed by 33-43 s, respectively. Among the 2225 rhythm sequences not judged as VF/VT the AED advised a shock on one occasion (0.04%). CONCLUSION: Among patients with coarse VF AED gave inaccurate instructions in 2.7%. However, the majority of the failures were judged to be caused by human errors.</p> <p><i>Review of AED data from 383 consecutive cardiac arrests allowed identification of errors. In 3 of 10 cases of failure to shock (in 375 analyses of coarse VF), low battery was cause; authors suggest careful oversight may prevent these.</i></p> <p><b>LOE 5 / Qual Excellent / Support</b></p>
<p>Kaye 1995</p>	<p>Kaye, W., M. Mancini, et al. (1995). "Organizing and implementing a hospital-wide first-responder automated external defibrillation program: strengthening the in-hospital chain of survival." <i>Resuscitation</i> <b>30</b>: 151-56.</p> <p>First-responder automated external defibrillation (AED) in the hospital is consistent with the American Heart Association's (AHA) early defibrillation standard of care. With trained personnel and automated external defibrillators immediately available, early defibrillation should have a greater impact on survival than early cardiopulmonary resuscitation (CPR). Therefore, in our hospitals we modified basic life support to include automated external defibrillation (BLS-AED) for all personnel who are expected to respond to a cardiac arrest, with rapid defibrillation taking priority over CPR. We describe how we organized and implemented this hospital-wide first-responder BLS-AED program. Planning the process includes gaining support from key leaders who are responsible for resuscitation practice, and identifying the target audience of the training program. Hospital unit needs for AED or conventional defibrillation and equipment must be identified, the training program developed, and existing policies and procedures modified. Several barriers to implementation may exist. Education about the efficacy and safety of AED and experience once the BLS-AED program is in place can overcome attitudes and bias. Concerns about the cost of equipment and training must be addressed. Program evaluation may include patient issues such as measuring the time to the first defibrillation and patient outcome; as well as training and retention issues.</p> <p><i>Authors with experience in hospital early defibrillation programs suggest program evaluation is essential, including review of outcomes (with consideration of confounding variables) and time to shock.</i></p> <p><b>LOE 8 / Qual Good / Support</b></p>
<p>Kellerman 1993</p>	<p>Kellermann, A. L., B. B. Hackman, et al. (1993). "Engineering excellence: options to enhance firefighter compliance with standing orders for first-responder defibrillation." <i>Annals of Emergency Medicine</i> <b>22</b>(8): 1269-75.</p> <p>STUDY OBJECTIVE: To assess the quality of care delivered during first-responder defibrillation and to determine the potential efficacy of modifying existing automated external defibrillator designs to improve first-responder performance. DESIGN: Prospective case series. SETTING: An urban emergency medical services system providing first-responder defibrillation and paramedic care. TYPE OF PARTICIPANTS: Firefighters who completed a four-hour (two-session) course in automated external defibrillator operation. METHODS: Heartstart 2000 defibrillators (Laerdal Medical Corp, Armonk, New York) were used in 241 consecutive resuscitation attempts. Written reports and memory module printouts were abstracted to assess firefighter performance of 11 critical actions. The firefighter's response to each opportunity to perform a critical action was scored using explicit pass/fail criteria. RESULTS: Records of 235 automated external defibrillator uses (97.5%) were submitted for analysis. Firefighters shocked within 15 seconds of a "shock indicated" message in 95% of opportunities and reanalyzed the rhythm within 90 seconds of the third consecutive shock (ie, after one minute of CPR) in 80% of cases. However, firefighters reanalyzed the patient's rhythm too soon in 75% of cases, thereby interfering with recommended intervals of CPR. Firefighters failed to reanalyze the patient's rhythm after device-initiated "check patient" prompts 62% of the time. Memory modules were left in the automated external defibrillator during practice sessions in 64 cases, decreasing available memory to monitor automated external defibrillator use in the field. Three instances of failure to withhold CPR during rhythm analysis resulted in a single inappropriate patient shock. No firefighter was shocked inadvertently. CONCLUSION: Current device algorithms result in effective delivery of the initial three shocks. However, firefighters often fail to interpose recommended intervals of CPR between further attempts at defibrillation. Modification of existing device algorithms to provide additional visual and auditory cues may be preferable to relying on the user to recall accurately all the steps in this infrequently performed</p> <p><i>Written reports and data recorded by AEDs reviewed in 241 consecutive cases of first responder response to cardiac arrests in urban system. Data was useful in assessing AED, responder and system performance and making recommendations for improvement, particularly for AED engineering enhancements.</i></p> <p><b>LOE 5 / Qual Excellent / Support</b></p>
<p>MacDonald 2001</p>	<p>Macdonald, R. D., J. M. Swanson, et al. (2001). "Performance and error analysis of automated external defibrillator use in the out-of-hospital setting." <i>Ann Emerg Med</i> <b>38</b>(3): 262-67.</p> <p>STUDY OBJECTIVE: We determined whether automated external defibrillators (AEDs) can meet the American Heart Association performance criteria to detect and shock unstable cardiac rhythms (ventricular fibrillation [VF], ventricular tachycardia [VT]) in the setting of an out-of-hospital cardiac arrest. METHODS: AED performance was reviewed for cardiac arrests occurring between January 1, 1995, and December 31, 1997. After every cardiac arrest, data</p>

	<p>regarding each rhythm analyzed and subsequent response (shock or no shock) were downloaded from the AED memory module. The study paramedic and study physician independently reviewed each case and interpreted cardiac rhythms from downloaded AED data. The emergency medical services medical director resolved all discrepancies in a blinded manner. All cases of out-of-hospital cardiac arrest in which an AED was turned on and a rhythm analyzed were included. The primary objective was the correct identification and defibrillation of VF or VT. Sensitivity, specificity, and predictive values with 95% confidence intervals (CIs) were calculated. Sources of error in AED rhythm management are also described. RESULTS: A total of 3,448 AED rhythms were available for interpretation. Sensitivity and specificity for appropriate AED management of a shockable (VF or VT) rhythm were 81.0% (95% CI 77.9% to 83.8%) and 99.9% (95% CI 99.7% to 100%), respectively. Positive and negative predictive values were 99.6% (95% CI 98.7% to 99.9%) and 95.5% (95% CI 94.7% to 96.2%), respectively. There were 132 errors associated with AED management. Two errors resulted in delivery of an inappropriate shock. In the remaining 130 errors, a shockable rhythm was not shocked. Fifty-five (42.3%) errors were AED dependent, 70 (53.9%) were operator dependent, and 5 (3.9%) were unclassified. CONCLUSION: The AED had high specificity and moderately high sensitivity in detecting and shocking unstable cardiac rhythms in the out-of-hospital setting. Few cardiac rhythms were mismanaged by the AED. Elimination of operator-dependent errors could increase AED sensitivity.</p> <p><i>This retrospective review of 3,448 AED rhythm analyses (in 1,079 out of hospital cardiac arrests) demonstrates the ability to use AED data to assess AED and operator performance and determine errors specific to each.</i></p> <p><b>LOE 5 / Qual Excellent / Support</b></p>
McDowell 1993	<p>McDowell, R., J. Krohmer, et al. (1993). "Guidelines for implementation of early defibrillation/automated external defibrillator programs. American College of Emergency Physicians." <i>Ann Emerg Med</i> <b>22</b>(4): 740-41.</p> <p><i>Guidelines from American College of Emergency Physicians endorse QI program including uniform data reporting for CA, case analyses, maintenance and evaluation of outcomes.</i></p> <p><b>LOE 8 / Qual Excellent / Support</b></p>
Ornato 1992	<p>Ornato, J. P., J. Shipley, et al. (1992). "Inappropriate electrical countershocks by an automated external defibrillator." <i>Ann Emerg Med</i> <b>21</b>: 1278-82.</p> <p>A 79-year-old man who was in normal sinus rhythm with a palpable pulse was inappropriately shocked twice by a fully automated external defibrillator. The second shock resulted in ventricular tachycardia. The device then countershocked a third time, restoring normal sinus rhythm. The problem occurred primarily because the rescuers did not follow the device's instructions warning against applying the device in analysis mode to a patient with a palpable pulse, and they attempted to analyze the rhythm in a moving vehicle. Motion artifact and T waves that were relatively tall compared with the QRS amplitude were misinterpreted as ventricular fibrillation by the device. This example of inappropriate countershocks delivered by rescuers using a fully automated device illustrates the importance of proper training and continuing education.</p> <p><i>Case report of inappropriate shock of normal sinus rhythm in patient with spontaneous pulse and respiration. Error attributed to inappropriate patient application. Demonstrates value of AED data to determine actual events and make corrective actions.</i></p> <p><b>LOE 5 / Qual Good / Support</b></p>
Priori 2004	<p>Priori, S., Bossaert, L, Chamberlain, D, Napolitano C, Arntz HR, Koster R, Monsieurs K, Capucci A, Wellens H. (2004). " Policy Statement:ESC-ERC recommendations for the use of AEDs in Europe." <i>Resuscitation</i> <b>60</b>: 245-52.</p> <p>No abstract</p> <p><i>ESC-ERC recommendations for use of AEDs endorses the value of and describes key components of data collection and assessment of program results. The report also makes specific maintenance and training recommendations.</i></p> <p><b>LOE 7 / Qual Excellent / Support</b></p>
Sunde 1999	<p>Sunde, K., T. Eftestol, et al. (1999). "Quality assessment of defibrillation and advanced life support using data from the medical control module of the defibrillator." <i>Resuscitation</i> <b>41</b>(3): 237-47.</p> <p>What actually occurred during the two last links in the 'chain of survival': defibrillation and advanced life support (ALS), was studied in 156 patients with cardiac arrest of cardiac aetiology using the computer recording of the defibrillator and the Utstein-style data record. Ten patients (6%) survived. The ECG artefacts caused by chest compressions enabled a detailed analysis of compression rates (median 108 min(-1)) and duration of important compression free periods. The time from initiation of monitoring during asystole until chest compressions were initiated was median 29 s, significantly shorter than during electromechanical dissociation (EMD, 109 s; P &lt; 0.001). These times were both significantly longer than the median time from initiation of monitoring until the first shock was given in cases with VF (19 s; P &lt; 0.001). A total of 883 shocks (median six shocks) were administered to 110 patients with a significant difference in number of shocks between survivors and non-survivors, one versus seven, respectively. The success rate for the first shock and all shocks defined as non-VT/VF 5 s after the shock, was 75 and 63%, respectively. However, just 10% of all shocks resulted in a rhythm with a pulse and only 4% resulted in sustained return of spontaneous circulation (ROSC). An isoelectric period followed 38% of the shocks, and in 27% this lasted more than 20 s, with five patients obtaining electrical activity with a pulse after more than 30 s of isoelectric ECG. Thoracic impedance did not affect the shock efficacy. The method of analysing resuscitation we describe may be useful for quality improvement.</p>

	<p><i>Authors report on usefulness and breadth of information obtained from review of AED recorded data and run reports. Rates and times of CPR were discernable on ECG recording.</i></p> <p><b>LOE 5 / Qual Excellent / Support</b></p>
Tan 2002	<p>Tan, K. S. and I. Hinberg (2002). "Investigation of capacitor failures in an automated external defibrillator." <u>Eur J Emerg Med</u> 9(3): 248-52.</p> <p>Over the past 2 years, the Canadian Medical Devices Bureau has received a number of reports of capacitor failures on the high voltage board of an automated external defibrillator. Twenty-five cases of broken capacitor leads were found during routine preventive maintenance by the biomedical engineering staff of the institutions reporting the incidents. The Bureau has carried out a laboratory investigation to determine the effect of missing capacitors on the energy delivered by the defibrillator and to assess whether these capacitor failures represent a significant risk to patients. Our findings indicate that the automated external defibrillator will not perform acceptably with two broken capacitors. They further suggest that, during preventive maintenance, operators should use a defibrillator analyser to measure the delivered energy output rather than using the internal energy measurement circuit within the automated external defibrillator.</p> <p><i>This study measured energy output from one AED model with capacitors intact, one disconnected (15% decrease), two disconnected (30% decrease) and one shorted (15% increase). The AED did not show alert after self-testing in above conditions so the defect would not be detected. Authors note that Canadian Medical Device Bureau has received a number of reports of capacitor failures from biomedical engineers after routine inspection of AEDs, and suggest that AEDs should be tested with a defibrillator analyzer rather than relying on internal testing mechanism of the device.</i></p> <p><b>LOE 7 / Qual Good / Support</b></p>
White 2001	<p>White, R. D. (2001). "Technologic advances and program initiatives in public access defibrillation using automated external defibrillators." <u>Curr Opin Crit Care</u> 7(3): 145-51.</p> <p>Widespread provision of early defibrillation following cardiac arrest holds major promise for improved survival from ventricular fibrillation. The critical element in predicting a successful outcome is the rapidity with which defibrillation is achieved. A worldwide awareness of this potential and its advocacy by such organizations as the American Heart Association have been pivotal in the evolution of initiatives to make defibrillation more widely and more rapidly available. The feasibility of this initiative, known as public access defibrillation, is in large measure a direct consequence of major technologic advances in automated external defibrillators (AEDs). New low-energy waveforms with biphasic morphology have been shown to be more effective in terminating ventricular fibrillation and may do so with less myocardial injury. Placement of AEDs in a variety of nontraditional settings such as police cars, aircraft and airport terminals, and gambling casinos has been shown to yield an impressive number of survivors of cardiac arrest in ventricular fibrillation. Questions yet to be answered center on the appropriate disposition of AEDs in public access defibrillation settings, training and retraining issues, device maintenance, and collection of accurate data to document benefit and to identify areas of needed improvement or expansion of AED availability.</p> <p><i>Experienced investigator endorses the value of collecting process and outcome data as imperative to understanding benefits and limitations of use of AEDs.</i></p> <p><b>LOE 8 / Qual Good / Support</b></p>
White 1993	<p>White, R. D. (1993). "Maintenance of defibrillators in a state of readiness." <u>Ann Emerg Med</u> 22(pt 2)(2): 302-06.</p> <p>Since 1984, the US Food and Drug Administration (FDA) has utilized the Medical Device Reporting system as a mechanism for reporting adverse incidents associated with the use of medical devices, including external defibrillators. The frequency and content of these reports prompted an FDA-conducted five-state study of defibrillator-user training and maintenance practices for both devices and batteries. The study also included inspection and testing of defibrillators and batteries to assess their state of maintenance. A detailed review of the reports and of the five-state data confirmed that in the majority of cases, adverse incidents were related to improper defibrillator operation and maintenance, prompting the FDA Center for Devices and Radiological Health to launch an educational effort directed toward those who operate and maintain defibrillators. Proper maintenance of batteries (both nickel-cadmium and sealed lead-acid) was a major component of the educational thrust, because battery failure was identified as a recurrent and preventable problem. In an effort to correct the diverse types of incidents being reported, checklists were developed by the FDA for both manual and automated defibrillators. The checklists are designed to cover the spectrum of reported problems related to both device and user. The advent of more stringent FDA adverse incident-reporting regulations, coupled with increased use of defibrillators in diverse settings with varying usage frequencies, would seem to give a major impetus to the regular use of these checklists wherever defibrillators are employed.</p> <p><i>Comment on FDA investigation of manual and automated external defibrillators that found most adverse incidents were related to improper defibrillator operation and maintenance of devices and batteries. Author suggests that FDA developed checklists will be helpful in reducing and understanding errors.</i></p> <p><b>LOE 7 / Qual Good / Support</b></p>

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(主任研究者 丸川征四郎)

平成18年度研究報告

分担研究

AED適応疾患に対する救急医療連携のあり方に関わる研究

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## 目 次

1. 研究者名簿 .....	3
2. 分担研究報告書 .....	3
研究要旨	
A. 研究目的	
B. 研究方法	
C. 研究結果	
D. 考 察	
E. 結 論	
F. 健康危険情報	
G. 研究発表	
H. 知的財産権の出願・登録状況	

資料 8-1 研究に用いるWebデータベース の概要について

資料 8-2 データベースにおける患者個人情報の取り扱いについて

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# AED適応疾患に対する救急医療連携のあり方に関わる研究

分担研究者 笠貫 宏 東京女子医科大学 循環器内科 教授

研究要旨：AED適応疾患として代表的な急性心筋梗塞が地域救急医療体制の中でどのように対応されているかについて、複数の地域（仙台、浜松、東京）で実態調査し、有機的な救急医療連携体制のあり方について提言する。その際には、入院した患者の記録、救急隊の記録、心筋梗塞発症のリスクとなる危険因子を有する患者に対する地域の医療機関での教育などを検討する。高度情報化社会でありXMLフォーマット等によるデータ管理を併用する。

## A. 研究目的

急性心筋梗塞においては心室細動の可能性と早期再灌流療法の有効性から、発症からできる限り早期にCCUに収容することが重要である。本研究の目的は、将来的にいかに発症から病院収容、初期治療までの時間を短縮できるかを検討することである。

## B. 研究方法

本研究では、基幹病院に入院した患者記録から、入院経路、発症から入院や再灌流治療までの時間経過を検討する。さらには、救急隊の資料から実際にAEDを用いた状況などについての検討し、地域の医療機関からは、心筋梗塞発症のリスクとなる危険因子を有する成人病患者に対する教育、啓蒙の実際について検討する。複数地域を予定しており、症例登録にインターネット上のデータベースとしてXMLデータを使用する(資料1)。計画は、1年目の関連2医療機関と周辺連携医療機関からのデータ交換のためのインフラ整備。2年目に仙台、浜松、東京においての患者情報収集を行い、3年目に収集された患者情報の解析としている。

(倫理面への配慮)

個人的データを扱うために当該個人が特定できないよう配慮した情報処理の方法、ならびに情報が漏洩しない管理体制を構築する(資料2)。

## C. 研究結果

現時点で、患者情報収集を開始していないために成果は無いが、XML形式のデータ収集を行うWebDatabase はほぼ完成した。

## D. 考察

本研究によって、1、急性心筋梗塞の早期収容のための提言をまとめる。2、救急疾患の症例登録のために有効なデータベースの1例となる。3、地域の成人病患者にたいする急性心筋梗塞発症時の対応について教育するサンプルとなりえることが期待される。

## E. 結論

急性心筋梗塞の早期収容のための提言を行う目的で救急疾患の症例登録のためにデータベースの構築を行った。

## F. 健康危険情報

なし

## G. 研究発表

なし

## H. 知的財産権の出願・登録状況

## 研究に用いるWebデータベース の概要について

本システムはWebデータベースのデファクトスタンダードLAMP（ランプ）系言語にて構築を行う。LAMPとは、OSであるLinux、WebサーバであるApache HTTP Server、データベースであるMySQL、スクリプト言語であるPHP、を総称した頭文字から成る造語である。動的（ダイナミック）なウェブコンテンツを含むウェブサイトの構築に適した、オープンソースのソフトウェア群である。これらは、それぞれ独自に開発されたものである。更にユーザーへの情報フィードバックにはXMLを用いて開発を行う。

### Linux（リナックス）

UNIXライクな（UNIXに似た）コンピュータ用オペレーティングシステム(OS)である。現在では、パーソナルコンピュータに限らず、携帯電話のような組み込みシステムからメインフレームやスーパーコンピュータまで、幅広く利用されている。

### Apache HTTP Server（アパッチ エイチティーティーピー サーバ）

世界中でもっとも使われているWebサーバソフトウェアであり、大規模な商用サイトから自宅サーバまで幅広く利用されている。単にApacheとも称されている。

### MySQL（マイエスキューエル）

RDBMS（リレーショナルデータベースを管理、運用するためのシステム）の実装の一つである。

### PHP（ピー・エイチ・ピー）

動的にHTMLデータを生成することによって、動的なウェブページを実現することを主な目的としたプログラミング言語、およびその言語処理系である。

### Extensible Markup Language（エクステンシブルマークアップランゲージ、XML）

拡張可能なマーク付け言語は、データを記述するマークアップ言語を定義するためのメタ言語である。現在では、パーソナルコンピュータに限らず、携帯電話のような組み込みシステムからメインフレームやスーパーコンピュータまで、幅広く利用されている。

これらのWeb構築開発技術は既に多くのWebデータベースにおいて活用されており、たとえばYahooなどにおいてもその堅牢性は検証されている。なお、ただ

し医学研究専用Webデータベース分野ではその特殊性からインターネット技術が浸透されておらず、またその技術応用するだけの技術組織がなかったためにいまだ活用事例は少ない。

地域医療情報連携ネットワーク - Microsoft Internet Explorer

ファイル(F) 編集(E) 表示(V) お気に入り(A) ツール(T) ヘルプ(H)

□ □ □ □ □ 1 6

## 地域医療情報連携ネットワーク

- 個人情報保護のため患者個人を特定できる可能性のある情報は掲載しておりません。
- Windows版Internet Explorer6.0、7.0以外では正しく表示・作動しません。
- Macintoshでは正しく表示・作動しません。
- 毎週木曜日午前0:00～4:00定期メンテナンスを実施しています。動作が不安定になる可能性があります。

- 詳細調査参加施設一覧の登録内容に誤りがないかご確認ください。
- 管理審査委員会申請は当ページの計画書、実施手順ページにある説明文書・同意書・症例報告書をご使用ください。
- 管理審査委員会の申請日および承認日はデータセンターまでご連絡ください。

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参加施設  
施設登録・修正  
実施手順  
登録数

問い合わせ先  
(データセンター)  
(STATZ Institute Inc.)

VeriSign  
Secured  
クリックして保証  
Security Policy

login

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## 資料 8 - 2

### データベースにおける患者個人情報の取り扱いについて

本システムは「医療・介護関係事業者における個人情報の適切な取扱いのためのガイドライン」を遵守し、患者個人情報の取り扱いに細心の注意をはらい実施される。本システムで扱われる情報においては「氏名」、「生年月日」、「住所」、「電話番号」および連結照合による個人特定の可能性を持つ「カルテ番号」を削除し匿名化を行う。共同研究機関内で患者個人と関わりのない符号あるいは番号を付し「連結匿名化」する。共同研究機関内にてはその施設内規定に応じ「連結匿名化リスト」は個人情報管理者によって厳重に施鍵管理される。共同研究機関外への「個人情報」、「個人に関する情報」および「連結匿名化リスト」の持ち出しを堅く禁止し、研究会全体での収集情報が「連結不可能匿名化」されることを保証する。本システムはインターネット技術を用いた情報収集システムを併用する上で「医療情報システムの安全管理に関するガイドライン」および「不正アクセス行為の禁止等に関する法律」を遵守し実施される。通信の128ビット暗号化（SSLセキュア・ソケット・レイヤー）、二重ログイン構成、予告なし不定期パスワード変更、悪意の第三者によるサイバーテロ攻撃等に対応策を講じて実施される。

#### 参考文献

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- 2)厚生労働省. 医療情報システムの安全管理に関するガイドライン. 2005.不正アクセス行為の禁止等に関する法律. 2000.

第1回

# 日本学生ALS大会

## JICAM

(Japan Inter-College ALS Meeting)



日本学生ALS大会 第1回大会実行委員会

本大会は、平成18年度厚生労働科学研究費補助金（循環器疾患等生活習慣病対策総合研究事業）による「自動体外式除細動器（AED）を用いた心疾患の救命率向上のための体制の構築に関する研究（課題番号 H18-心筋-01）」の分担研究「自動体外式除細動器（AED）を用いた心疾患の救命率向上のための体制の構築に関する研究」（丸川分担研究班）の一環として行われました。

# 第1回 日本学生ALS大会

1 st annual meeting  
of  
Japan inter-college ALS meeting (JICAM)

日時 平成19年3月3日 13:00-17:00  
場所 神戸国際コンベンションホール  
主催 日本学生ALS大会 第1回大会実行委員会  
後援 日本集中治療医学会 第34回学術集会

## 日本学生ALS大会 第1回大会実行委員会

滋賀医科大学	医学部	4学年次	十倉	満
京都大学	医学部	4学年次	渡邊	翼
滋賀医科大学	医学部	4学年次	兼平	沙矢
大阪市立大学	医学部	4学年次	中村	通孝
大阪医科大学	医学部	4学年次	富岡	淳
大阪市立大学	医学部	5学年次	奥	友久



## 目 次

はじめに	十倉 満	1
1、企画と運営の理念	渡邊 翼	2
2、プログラム策定の経緯	兼平 沙矢	5
3、討論「学生がALSを学ぶ意義について」	中村 通孝・富岡 淳	
A. 討論の形式（KJ法を用いたグループ別討論）		11
B. 各グループの発表内容		15
C. 全体討論（前半）の記録		20
D. 全体討論（後半）の記録		24
E. 総括（コンセンサスに代えて）		28
4、特別企画①		
「川崎さんからの手紙とDVD」	富岡 淳	30
5、特別企画②		
「大阪市立大学BLS普及への取り組み」	田中 寛大	35
おわりに	十倉 満	36
参考資料1：アンケート集計結果	十倉 満	37
参考資料2：大会記録写真	宇高 千恵	43

## はじめに

滋賀医科大学 医学部4学年次 十倉 満

第1回日本学生ALS大会 (Japan inter-college ALS meeting ; JICAM) は、日本集中治療学会会長・日本版救急蘇生ガイドライン策定小委員会委員長の丸川征四郎先生と日本救急医療財団心肺蘇生法委員会委員長・策定小委員会副委員長の坂本哲也先生の全面的な支援のもと、関東、関西、北陸、東海、中国、四国、九州など、全国各地からALSやBLSを学ぶ学生が集結して開催され、各地の活動紹介、学生がALSを学ぶ意義についての討論が行われました。この大会は次のような主旨のもと行われました。蘇生科学に関するエビデンスに基づく初めてのガイドラインである、G2000 (guideline 2000) が発表されて以来、我が国でも多くの心肺蘇生に関する講習会が開かれてきました。また2005年には新たなエビデンスに基づく国際的なコンセンサスであるC2005 (consensus 2005、いわゆるCoSTR) が発表され、それをもとにアメリカ、ヨーロッパ、そしてわが国でも新たなガイドラインが発表されています。このような国際的な流れの中、学生にあっても心肺蘇生を学び隣人の命を救いたいという思いから、日本各地でBLSやALSを学ぶワークショップ (WS) が次々と開催されてきました。そして、今まで各地で独自にWSを行っていた学生が一堂に会する日本学生ALS大会が開催されることとなりました。各地で活躍する学生が一堂に会し、各地の活動を紹介し合い、今後の活動について討論するという事は、交流と相互理解そして相互刺激という点において大きな意義があるのではないのでしょうか。そして大会のテーマ“学生ALSを考える”は、これまでとは違った視点から学生の学ぶALSをとらえ、その意義と価値を見つめなおし、今後の活動のあり方を模索しようという試みを意味しています。この大会で形成されるコンセンサスが、今後の学生の学ぶALSの方向性を示し、さらなる普及・発展にむけての新たな視野を広げ、活動を担う一人一人に大きな効果をもたらすことを願っています。

(しおりから抜粋・加筆)

# 1. 企画と運営の理念

京都大学医学部 4学年次 渡邊 翼

## A. プログラム

当日のプログラムを掲示し、続いて企画から当日の運営までの流れを記載します。

第1回学生ALS大会 (Japan Inter-College ALS Meeting: JICAM) 開催日時 2007年3月3日 12:00~17:00	
<プログラム>	
12:00~13:00	受付・会場準備開始
13:00~13:10	オープニング
13:10~13:50	関西・関東地区 ワークショップ紹介およびデモンストレーション
13:50~14:00	北陸・東海地区 ワークショップ紹介
14:00~14:55	<u>討論テーマ①「学生がALSを学ぶ意義」</u>
(14:00~14:15	グループ討論
14:15~14:25	全体へ発表
14:25~14:45	全体討論
14:45~14:55	企画)
14:55~14:05	休憩
15:05~15:15	四国・中国地区 ワークショップ紹介
15:15~15:35	<u>討論テーマ②「学生ALS・WSの質の維持」</u>
15:35~15:40	九州地区 ワークショップ紹介
15:40~16:00	<u>討論テーマ③「学生ALS・WSの展望」</u>
16:00~16:10	企画
16:10~16:25	コンセンサス発表・閉会の挨拶
16:25~16:30	コメンテーターの挨拶
16:30~17:00	撤収
17:00	完全撤収

## B. 企画に当たって

当初、プログラムを組むにあたり、何よりも主催者側は中立の立場を取るべきであるとの基本的な姿勢を確認しました。つまり、予め用意した答えを参加者に押しつけるような形にはせず、討論の現場で交わされる議論から見解を形成することです。

現在、学生インストラクターと参加者あわせて150名以上の大イベント、『第14回関西ALSワークショップ』の運営を企画している段階であり、このワークショップを成功させる方策を考えているちょうどこの過程で、このJICAM開催の発案を受けま

した。

企画に当たっては、『こうした方がよいだろう』『このプログラムには主催者側のこのような意思が入ってしまうではないか』このような議論が幾度となく交わされ、学会会長の丸川先生との打ち合わせも綿密に行い、改訂に改訂を重ねた結果、ようやくプログラムが完成しました。この企画段階での議論は、この大会の意義と今後の活動を考える上で、貴重な体験であったと思います。

プログラムに組み込まれた議題は3つありました。

- (1) 学生がALSを学ぶ意義について
- (2) 学生が開くワークショップの質の維持をどのようにすればよいか
- (3) 学生ALSの展望はどんなものがあるのか

#### C. プログラム変更の経緯

- 1) プログラム編成にあたって問題となったのは特別企画でした。

今回、特別企画として予定していたものは以下の2つでした。

- ① 企画名『川崎さんからの手紙とDVD』

これは、突然の心停止により娘を失った母親の気持ちを綴った手紙です。母親がAEDとその使用方法の普及のためにと協力してくださって初めて可能となった企画で、今回JICAMのプログラムを組むにあたり、『自分たちが行っている活動の意味』を考える動機付けになればと企画しました。

- ② 企画名『大阪市立大学BLS普及への取り組み』

これは、現在大阪市立大学のLife support clubという団体が中心となって活動していることを参加した皆さんに知ってもらうための企画です。詳しくは、大阪市立大学 田中寛大のレポートにゆずります。

#### D. 各地のワークショップ紹介

各地のワークショップの様子を紹介してもらいました。パソコンのテクニックを駆使して見るも鮮やかな動画での説明や、学生らしさを出し、おもしろおかしく笑いを取りつつ、真剣に活動の内容や経緯を語る発表もありました。各地のワークショップの特徴を交えた発表やデモンストレーションはわかりやすく、会場も盛り上がりました。

#### E. 討論の流れ

第一の議題は『学生がALSを学ぶ意義について』です。

議長のテンポの良い指揮にあわせて、まずは各ブースごとに個々の意見を出し合いました。そして、ブースごとの発表に移りました。ブースごとの発表を踏まえたうえで全体討論にうつりました。全体討論ではそれぞれの熱意と意見の違いが浮き彫りに