

Quality of Cardiopulmonary Resuscitation During Out-of-Hospital Cardiac Arrest

Lars Wik, MD, PhD

Jo Kramer-Johansen, MD

Helge Myklebust, BEng

Hallstein Sørebo, MD

Leif Svensson, MD

Bob Fellows, MD

Petter Andreas Steen, MD, PhD

SINCE THE FIRST STANDARDS AND guidelines for cardiopulmonary resuscitation (CPR) were published 30 years ago¹ (with the latest update in 2000^{2,3}) health care professionals in and out of the hospital have been trained accordingly around the world. The importance of CPR, defined as chest compressions and ventilation, for survival of cardiac arrest patients has been demonstrated,⁴ and there are indications that the quality of CPR performance influences the outcome.⁵⁻⁷

When tested on mannequins, CPR quality performed by lay rescuers and health care professionals tends to deteriorate significantly within a few months after training,⁸⁻¹⁰ but little is known about the quality of clinical performance on patients. Aufderheide et al¹¹ recently observed short periods with inappropriately high ventilation rates during advanced cardiac life support (ACLS), and van Alem et al¹² found long pauses in CPR when first responders used automated external defibrillators.

We therefore studied the performance of paramedics and nurse anesthetists during out-of-hospital ACLS by continuously monitoring all chest compressions and ventilations during re-

See also pp 305 and 363, and Patient Page.

Context Cardiopulmonary resuscitation (CPR) guidelines recommend target values for compressions, ventilations, and CPR-free intervals allowed for rhythm analysis and defibrillation. There is little information on adherence to these guidelines during advanced cardiac life support in the field.

Objective To measure the quality of out-of-hospital CPR performed by ambulance personnel, as measured by adherence to CPR guidelines.

Design and Setting Case series of 176 adult patients with out-of-hospital cardiac arrest treated by paramedics and nurse anesthetists in Stockholm, Sweden, London, England, and Akershus, Norway, between March 2002 and October 2003. The defibrillators recorded chest compressions via a sternal pad fitted with an accelerometer and ventilations by changes in thoracic impedance between the defibrillator pads, in addition to standard event and electrocardiographic recordings.

Main Outcome Measure Adherence to international guidelines for CPR.

Results Chest compressions were not given 48% (95% CI, 45%-51%) of the time without spontaneous circulation; this percentage was 38% (95% CI, 36%-41%) when subtracting the time necessary for electrocardiographic analysis and defibrillation. Combining these data with a mean compression rate of 121/min (95% CI, 118-124/min) when compressions were given resulted in a mean compression rate of 64/min (95% CI, 61-67/min). Mean compression depth was 34 mm (95% CI, 33-35 mm), 28% (95% CI, 24%-32%) of the compressions had a depth of 38 mm to 51 mm (guidelines recommendation), and the compression part of the duty cycle was 42% (95% CI, 41%-42%). A mean of 11 (95% CI, 11-12) ventilations were given per minute. Sixty-one patients (35%) had return of spontaneous circulation, and 5 of 6 patients discharged alive from the hospital had normal neurological outcomes.

Conclusions In this study of CPR during out-of-hospital cardiac arrest, chest compressions were not delivered half of the time, and most compressions were too shallow. Electrocardiographic analysis and defibrillation accounted for only small parts of intervals without chest compressions.

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suscitation episodes using online defibrillators modified to collect such data.

METHODS

Patient Inclusion and Recruitment

The study was approved by the regional ethics committees for Akers-

hus, Norway, Stockholm, Sweden, and London, England. Informed consent for inclusion in the study was waived as decided by these committees in accordance with paragraph 26 in the Declaration of Helsinki.¹³ The study was a case series involving patients older than

Author Affiliations: National Competence Center for Emergency Medicine (Dr Wik), Institute for Experimental Medical Research (Drs Wik, Kramer-Johansen, and Steen), Division of Prehospital Emergency Medicine (Drs Wik, Sørebo, and Steen), and Division of Surgery (Dr Steen), Ullevål University Hospital, Oslo, Norway; Norwegian Air Ambulance, Department of Research and Education in Acute Medicine, Drøbak, Norway (Dr Kramer-Johansen); Laerdal Medical, Corp, Stavanger,

Norway (Mr Myklebust); Sodersjukhuset, Stockholm, Sweden (Dr Svensson); London Ambulance Service NHS Trust, London, England (Dr Fellows).

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Corresponding Author: Lars Wik, MD, PhD, NAKOS, Institute for Experimental Medical Research, Ullevål University Hospital, N-0407 Oslo, Norway.

18 years with out-of-hospital cardiac arrest of all rhythms. Noncardiac causes of cardiac arrest were included. Patients with cardiac arrest occurring between March 2002 and October 2003 were included in the study.

Equipment

Prototype defibrillators based on Heartstart 4000 (Philips Medical Systems, Andover, Mass) were deployed in 6 ambulances in each of the 3 regions. These ambulances were chosen based on historically high rates of cardiac arrest at their sites. The defibrillators were fitted with an extra chest pad to be mounted on the lower part of the sternum with double adhesive tape. This chest pad was fitted with an accelerometer (ADXL202e, Analog Devices, Norwood, Mass) and a pressure sensor (22PCCFBG6, Honeywell International Inc, Morristown, NJ). The heel of the rescuer's hand was placed on top of the chest pad and movement of the chest pad was considered equal to that of sternal movement during chest compressions. To avoid registering movements of the entire patient as chest compressions, only movements of the sternal chest pad with a parallel compression force greater than 2 kg were used in the automated analysis. A second accelerometer of the same kind was fitted within the defibrillator. Signals from this accelerometer were subtracted from signals from the chest pad accelerometer prior to depth calculation to compensate for possible vertical motion of the entire supporting surface. This technology has previously been reported to measure chest compression depth with an accuracy of ± 1.6 mm.¹⁴

Treatment Protocol

All ambulances were staffed by paramedics; in Stockholm, the second rescue vehicle at the scene also included a nurse anesthetist. Immediately prior to the study period, all involved personnel underwent a refresher course in ACLS according to international CPR guidelines^{2,3} and in use of the modified defibrillator. In Akershus, a modification required that patients with ven-

tricular fibrillation or pulseless ventricular tachycardia received 3 minutes of CPR before the first direct current shock and between unsuccessful series of 3 direct current shocks.¹⁵ Resuscitation was otherwise attempted in accordance with the guidelines.^{2,3} The defibrillators were used in manual mode in Akershus and in semiautomatic mode in the 2 other regions. The personnel were aware that we intended to study CPR performance and that the sternal pad recorded chest compressions. They were not informed that a primary focus was duration of time CPR was performed.

Data Collection and Processing

Data from each resuscitation episode were collected in 2 data cards; 1 standard card collected electrocardiographic signals, time, and events, and a second card fitted specially for this study recorded signals from the extra chest pad and thoracic impedance between the defibrillator pads as measured by applying a nearly constant sinusoidal current. After each CPR episode, all data were extracted and collected and the memory of the cards was cleared. One person at each site was responsible for this.

The raw data consisted of timeline and events, electrocardiographic signals, thoracic impedance, and values from the extra chest pad, all sampled at 500 Hz. For each episode, a copy of the ambulance record and other written documentation, including the Utstein format for out-of-hospital cardiac arrest,¹⁶ were collected. All data were collected on a designated server at the facilities of Laerdal Medical Corp, Stavanger, Norway, and Laerdal personnel preprocessed the data by filtering and down-sampling to 50 Hz to facilitate display of the data for annotation and review. A custom-made computer program designed for the study (Sister Studio, Laerdal Medical) was used to view and annotate each cardiac arrest case. A second standard computer program (CodeRunner Web Express, Philips Medical, Andover, Mass) was used in parallel to provide further de-

tails about electrocardiography. For each episode, the initial rhythm and each subsequent change in rhythm were annotated. Pulseless electrical activity was defined as QRS complexes without blood flow, indicated either by a clinically detected pulse or blood flow-induced changes in thoracic impedance. Impedance changes coincident with cardiac contractions and arterial pressure pulses have been validated with echocardiography and blood pressure measurements in pigs.¹⁷ In a pilot study, we found these changes to be in the range of 87 to 477 m Ω in 21 healthy volunteers, and an impedance amplitude of greater than 50 m Ω was used to indicate blood flow in the present study.

Spontaneous circulation was defined as QRS complexes with blood flow as indicated by the same factors. Time markers were set at the start of the first chest compression, 5 minutes thereafter, and at the end of the resuscitation episode, defined as discontinued monitoring or the end of treatment as judged from recordings and written information. The term *time* is used for time intervals in this article and *time point* for a specific point in time. The annotations were made by an experienced anesthesiologist with training and clinical practice in ACLS together with a research engineer with working knowledge of the Sister Studio program and the measurement systems.

Compressions were calculated by integrating the difference between the 2 accelerometers over a time window defined by the 2-kg threshold from the force transducer. Compression depth was characterized as appropriate for 38 to 51 mm (1.5-2 in),^{2,3} too deep, or too shallow. Incomplete compression release was annotated if the chest pad pressure did not fall below 4 kg at any time during the compression-decompression cycle. Duty cycle was defined as the percentage of time with downward movement of the chest pad divided by the total cycle time. For each time period, the actual number of compressions per minute as well as the rate during compression periods (defined as

a period with <1.5 seconds between 2 compressions) were determined. No-flow time (NFT) was defined as total time minus the time with chest compressions or spontaneous circulation ($NFT = time_{total} - time_{compressions} - time_{spontaneous\ circulation}$), and the ratio between NFT and the total time without spontaneous circulation was defined as the no-flow ratio (NFR) [$NFR = NFT / (time_{total} - time_{spontaneous\ circulation})$]. The NFT and NFR represent the total time during the resuscitation episode without cerebral and myocardial circulation.

According to the guidelines,^{2,3} chest compressions should not be given during rhythm analysis, defibrillator charging, shock delivery, and pulse checks. Adjusting the NFT by subtracting the time required for these procedures ($NFT_{adj} = NFT - time_{defibrillator}$) thus indicates time without blood flow due to performance of the rescuer team without interfering with rhythm analysis, defibrillation attempts, or pulse checks. Time_{defibrillator} was determined for each episode. With the defibrillator in semi-automatic mode, actual recorded times from the defibrillator for automatic analysis, charging, and shock delivery were used. In manual mode, a maximum of 5 seconds was allowed for rhythm analysis. If an organized rhythm was present, palpation of pulse was allowed for a maximum of 10 seconds and included in time_{defibrillator} [$NFR_{adj} = NFT_{adj} / (time_{total} - time_{spontaneous\ circulation})$].

The NFT_{adj} and NFR_{adj} represent the potential for reducing time without circulation without interfering with guidelines recommendations^{2,3} and are less than the unadjusted values, which include NFT, as recommended in the guidelines.

Ventilations were automatically detected by changes in thoracic impedance, filtered and corrected for compression and blood flow-related signals. Ventilation measurement by impedance has been reported in many studies since 1944¹⁸ and was recently validated for the use of defibrillator electrodes during cardiac arrest in pigs.¹⁷ A recent study using the present defibrillator setup in volunteers

Table 1. Demographic and Annual Resuscitation Data for the 3 EMS Systems Investigated

	Akershus	London	Stockholm	Total
Demographic data				
Resuscitation episodes, No.	66	54	56	176
Male, No. %	42 (65)	40 (76)	47 (84)	129 (74)
Age, mean (SD), y (4 cases missing data)	68 (14)	65 (17)	70 (13)	68 (15)
Witnessed arrest, No. (%) (3 cases missing data)	54 (82)	35 (66)	37 (69)	126 (73)
Bystander CPR, No. (%)*	30 (51)	13 (25)	18 (35)	61 (37)
Response time, mean (95% CI), min*	9 (7-10)	6 (5-6)†	8 (7-9)	7 (7-8)
No. of shocks, median (95% CI)	2 (1-5)	1 (0-2)	2 (0-2)	1.5 (1-2)
Episodes with ≥1 shock, No. (%)	43 (65)	28 (52)	33 (59)	104 (59)
No. of shocks in episodes with ≥1 shock, median (95% CI)	5 (3-7)	6 (2-10)	4 (2-8)	5 (3-7)
Annual data				
Land area, km ²	4587	1605	3472	...
Population, No.	493 000	7 200 000	1 680 000	...
Men, %	48	48	49	...
Older than 65 y, %	13	12	16	...
CPR attempts per million/y	373	590	292	...
Discharged from hospital, %‡	12	5	6	...

Abbreviations: CI, confidence interval; CPR, cardiopulmonary resuscitation; EMS, emergency medical service. Ellipses indicate data not applicable.

*Twelve cases with ambulance-witnessed cardiac arrests were excluded.

†Response time was significantly shorter in London ($P < .05$ by 1-way analysis of variance with Bonferroni correction for multiple comparisons).

‡The denominator for hospital discharge data is the total number of cardiac arrests with presumed cardiac origin for patients older than 18 years.

showed strong correlation between impedance and spirometer waveforms.¹⁹

Outcome Measure

The primary outcome measure was adherence to international guidelines for CPR. Target values for compression rate were 100/min to 120/min; for depth, 38 to 52 mm; and for ventilation rate, 2 ventilations for every 15 compressions before intubation and 10/min to 12/min after intubation.

Statistical Analysis

All data from each resuscitation episode were collected and described using a spreadsheet program (Excel 2002, Microsoft Corp, Redmond, Wash) and a statistical analysis program (SPSS 12.0.1, SPSS Inc, Chicago, Ill). All statistical analyses were performed by J.K.-J. at the University of Oslo, Oslo, Norway. All numbers are given as mean (standard deviation) for the first 5 minutes after the start of recorded CPR and for the entire resuscitation episode. When variables had very skewed distributions, medians were used as the mid-point estimate and interquartile

ranges as the variability measure. The results for the first 5 minutes of the resuscitation episode were analyzed vs the rest of the episode by a paired 2-sided *t* test, and 95% confidence intervals (CIs) are presented for these variables.

RESULTS

The annual statistics and demographic data from the 3 emergency medical service systems are shown in TABLE 1. The outcomes according to initial rhythm for patients in this study are shown in TABLE 2.

Of the total 243 episodes correctly included, 67 were excluded because of incompleteness of data. The main reasons for exclusion were failure to apply the additional chest pad (35/67) and technical problems with the 2 data cards or the defibrillator pads (26/67). In 13 episodes, signal quality made ventilation count impossible; thus, ventilation data are reported for 163 episodes.

Compression data are summarized in TABLE 3. For the first 5 minutes and for the entire resuscitation episode, the

mean (SD) fractions of the time without CPR (NFR) were 49% (21%) and 48% (18%), respectively, and when subtracting the time necessary for analysis and defibrillation, the NFR_{adj} were 42% (19%) and 38% (17%), respectively. There was no difference in the mean NFR in the first 5 minutes vs dur-

ing the rest of the episode (49%; 95% CI, 46%-52% vs 50%; 95% CI, 47%-54%; *P* = .58), but there was a significant difference in NFR_{adj} (42%; 95% CI, 39%-45% vs 38%; 95% CI, 35%-41%; *P* = .004).

For the first 5 minutes and for the entire resuscitation episode, mean (SD)

compressions were 60/min (25/min) and 64/min (23/min), respectively, significantly lower during the first 5 minutes than during the rest of the episode (60/min; 95% CI, 57-64/min vs 65/min; 95% CI, 61-69/min; *P* = .02). There were no significant differences with time for any other variables. For the first 5 minutes and for the entire resuscitation episode, mean (SD) chest compression rates were 120/min (20/min) and 121/min (18/min); mean (SD) compression depth was 35 mm (10 mm) and 34 mm (9 mm); the mean (SD) percentages of compressions with a depth between 38 and 51 mm were 27% (30%) and 28% (25%); and the mean (SD) percentages of inappropriately shallow compressions were 59% (37%) and 62% (33%). The compression parts of the duty cycle were 41% (5%) and 42% (4%). Incomplete release occurred after a median (interquartile range) of 0% (0%-1%) and 0% (0%-2%) of the compressions. During the first 5 minutes, there was no occurrence of incomplete release of compressions in 101 of 173 episodes (58%), and in only 16 episodes, more than 10% of the compressions had incomplete release. Mean (SD) ventilations were 8/min (4.6/min) and 11/min (4.7/min) for the first 5 minutes and for the entire episode, respectively (Table 3).

A total of 61 patients (35%) achieved return of spontaneous circulation, 34 (19%) were admitted to the hospital, and 6 (3%) were discharged from the hospital. Five of 6 patients who survived to hospital discharge had nearly normal neurological function (Table 2). Survival according to CPR quality indicators for patients with ventricular fibrillation as initial rhythm are presented in TABLE 4.

Table 2. Outcomes According to Initial Cardiac Rhythm for All Causes of Cardiac Arrest*

Initial Cardiac Rhythm	All (n = 243)	Usable (n = 176)	ROSC‡	Admitted Alive ‡	Discharged Alive (n = 176)†‡
VF	98 (40)	75 (43)	31 (41)	19 (25)	6 (8)
Asystole	91 (37)	64 (36)	15 (23)	8 (13)	0
PEA	54 (22)	37 (21)	15 (41)	7 (19)	0
Total	243 (100)	176 (100)	61 (35)	34 (19)	6 (3)

Abbreviations: PEA, pulseless electric activity; ROSC, return of spontaneous circulation; VF, ventricular fibrillation.

*All data are expressed as No. (%).

†Five of 6 patients discharged alive had nearly normal neurological function (Cerebral Performance Category [CPC] 1: conscious, alert, normal cerebral function), and 1 was awake and oriented but reliant on others for activities of daily living (CPC 3: conscious, at least limited cognition, dependent on others for daily support).¹⁶

‡Denominators for percentages shown in these columns are the 75, 64, 37, and 176 patients with usable data for VF, asystole, PEA, and total, respectively.

Table 3. Performance of CPR During the First 5 Minutes and Entire Episode of CPR*

	First 5 Minutes of CPR	Entire Episode of CPR
No flow (n = 176)		
NFR, %	49 (21)	48 (18)
NFR _{adj} , %	42 (19)	38 (17)
Compression (n = 176)†		
Compressions/min	60 (25)	64 (23)
Compression rate, /min	120 (20)	121 (18)
Depth per episode, mm	35 (10)	34 (9)
38-51 mm with complete release	27 (30)	28 (25)
Too deep (>51 mm), median (IQR)	0 (0-3)	0 (0-5)
Too shallow (<38 mm)	59 (37)	62 (33)
Incomplete release, median (IQR), %	0 (0-1)	0 (0-2)
Duty cycle, %	41 (5)	42 (4)
Ventilation (n = 163)		
Ventilations/min	8 (4.6)	11 (4.7)

Abbreviations: CPR, cardiopulmonary resuscitation; IQR, interquartile range; NFR, no-flow ratio, the time without CPR as a percentage of the time without spontaneous circulation; NFR_{adj}, no-flow ratio, adjusted by subtracting time allowed for electrocardiographic analysis, possible defibrillation, and required pulse checks in the numerator.

*All data are expressed as mean (SD) unless otherwise noted.

†Compressions per minute refer to the actual number of compressions delivered per minute whereas compression rate refers to the mean rate of compressions, ie, the reciprocal of intervals between compressions in compression sequences.

Table 4. Quality of CPR Performance During the First 5 Minutes of CPR by Survival to Hospital Discharge for Patients With Ventricular Fibrillation as Initial Rhythm (n = 75)

	Discharged Alive, Mean (95% Confidence Interval)		<i>P</i> Value
	No (n = 69)	Yes (n = 6)	
NFR, %	49 (44-55)	40 (20-61)	.34
NFR _{adj} , %	40 (35-44)	32 (11-53)	.35
Depth of compressions, mm	38 (35-41)	38 (25-52)	.89
Ventilations/min	9 (7-10)	8 (5-12)	.94

Abbreviations: CPR, cardiopulmonary resuscitation; NFR, no-flow ratio, the time without CPR as a percentage of the time without spontaneous circulation; NFR_{adj}, no-flow ratio, adjusted by subtracting time allowed for electrocardiographic analysis, possible defibrillation, and required pulse checks in the numerator.

COMMENT

In this study of 176 adults with out-of-hospital cardiac arrest, chest compressions were given only half of the available time during these resuscitation events. Van Alem et al¹² reported that police and firefighters performed CPR a mean (SD) of only 45% (15%) of the duration during a median of 5 min-

utes of resuscitation before ambulance personnel took over. In that study, two thirds of the time without CPR could be explained by programmed interruptions from automated defibrillators. In our present study, CPR was performed by paramedics and nurse anesthetists, and only 15% to 20% of the time without CPR could be attributed to defibrillator use and required pulse checks. The periods without chest compressions and the relatively shallow compressions are not easily explained by focus on other tasks such as intubation or placement of an intravenous cannula. These interventions should occur during the initial minutes of ACLS, and there were only small differences in the results for the first 5 minutes and the rest of the episodes.

Only good-quality CPR improved the chance of survival in 3 studies of cardiac arrest patients.⁵⁻⁷ Chest compressions appear to be the most important factor, both in human⁶ and animal studies,^{20,21} and even short 4- to 5-second interruptions in chest compressions decrease coronary perfusion pressure.²² In addition to periods without chest compressions, more than half of chest compressions given in the present study were too shallow, indicating less-than-optimal circulatory effect of the CPR given. Arterial blood pressure increases with increasing compression force in humans,²³ and coronary blood flow increases with increasing compression depth from 38 mm to 64 mm in large pigs.²⁴ Most compressions in the present study were less than the recommended depth. This is in contrast with mannequin studies of professional rescuers, in which 30% to 50% of the compressions were too deep.^{25,26}

In addition to compression depth, blood flow is dependent on compression rate, compression/decompression ratio, and low intrathoracic pressure in the decompression phase, avoiding "leaning" on the chest by the rescuer. In canine and swine models, highest blood flows are reported with chest compression rates of 90/min to 120/min,²⁷⁻²⁹ leading to the guidelines recommendation of 100/min.^{2,3} Mean

compression rate tended to be too high in the present study, which might decrease cardiac output because of insufficient time for venous return to the heart during the decompression periods. "Leaning" on the chest wall during compressions was not a serious problem, although we cannot exclude that pressures lower than the 4 kg used to define leaning in the present study could have an unwanted effect. The compression/decompression ratio was satisfactory, with 41% to 42% compression time. The main problems were the long periods without any chest compressions and the shallow compression depth.

We did not find abnormally high ventilation rates, although we recorded the rate average over a minimum of 5 minutes. In contrast, Aufderheide et al¹¹ recently reported average ventilation rates of 30/min (3/min) with maximal rates during any 16-second period.¹¹ In animal models, ventilatory rates of 30/min vs 12/min decreased coronary perfusion pressure and also appears to decrease survival if sustained for 4 minutes.¹¹

Training programs for CPR have been implemented worldwide during the last 4 decades following guidelines from the American Heart Association² and the European Resuscitation Council.³ These programs specify criteria for correct performance of CPR, but neither the effects of such training programs on clinical CPR nor the effects of specific criteria or overall quality of ACLS on patient survival have been clinically documented. The present study was not powered to evaluate the effects of quality of CPR in a proper multivariate analysis with other factors known to influence survival, such as initial rhythm. A crude comparison between survivors and nonsurvivors with ventricular fibrillation as initial rhythm showed a tendency toward relatively less time without chest compressions among survivors, with no difference in compression depth or ventilation rate (Table 4).

All paramedics and nurse anesthetists in the present study had previous

ACLS training with regular retraining, and all underwent a refresher course immediately prior to study initiation. Some of the deviations from the international 2000 guidelines^{2,3} could be due to lack of knowledge retention, as most studies have reported deterioration in the performance of CPR within a few months after a course.^{8,10,30} The failure to perform chest compressions half the available time has not been reported in such studies, but they are all in mannequins,^{8,10,30} not in patients. It is possible that the highly complex physical and mental situation of treating a patient with cardiac arrest is too different from the training situation on mannequins, making the performance dramatically different and possibly less efficient. Based on this, the extrapolation from mannequin performance can be questioned, and as a recent international consensus document states, there is an urgent need to promote better CPR and improve the way CPR is taught.³¹

Whatever the reason, the resuscitation performance we measured was dramatically different from that recommended in the ACLS guidelines. It is tempting to question the focus on and the importance of details such as ventilation/compression ratios of 1:5 or 2:15 or biphasic vs monophasic defibrillators in our efforts to adjust evidence-based CPR guidelines, if the performance of vital skills is so far from the guidelines recommendations.

Whether some of these deficiencies can be improved by specific focus during training needs attention. Through better understanding of the mistakes made in a real-life cardiac arrest situation, training courses might be designed to focus on these aspects. Another approach would be to develop online tools that prompt the rescuer to improved performance. Audiotapes giving instructions on chest compression rate have been reported to improve the compression rate during cardiac arrest in patients.¹⁶ In mannequin studies, audio feedback based on continuous online automated evaluation dramatically improved CPR performance within the first 3 minutes.^{32,33} Ac-

ording to the international consensus, the ideal would be to have identically configured aids during both training and resuscitation attempts.³¹

If our study represents how CPR is delivered during resuscitation from out-of-hospital cardiac arrest in other communities, there is a great opportunity to improve CPR quality and, hopefully, patient survival by focusing on delivery of chest compressions of correct depth and rate, with minimal "hands-off" periods.

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Study concept and design: Wik, Kramer-Johansen, Myklebust, Steen.

Acquisition of data: Kramer-Johansen, Myklebust, Sørebo, Svensson, Fellows.

Analysis and interpretation of data: Wik, Kramer-Johansen, Myklebust, Svensson, Steen.

Drafting of the manuscript: Wik, Kramer-Johansen, Myklebust, Steen.

Critical revision of the manuscript for important intellectual content: Wik, Kramer-Johansen, Myklebust, Sørebo, Svensson, Fellows, Steen.

Statistical expertise: Kramer-Johansen.

Obtained funding: Myklebust, Svensson, Steen.

Administrative, technical, or material support: Wik, Myklebust, Svensson, Fellows, Steen.

Study supervision: Wik, Myklebust, Sørebo, Svensson, Fellows, Steen.

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required for data handling at study sites, and for all travel to study sites and investigator meetings. All other funding was obtained from the following independent foundations: Norwegian Air Ambulance Foundation, Laerdal Foundation for Acute Medicine, and Jahre Foundation. As stated in the protocol, Laerdal Medical could not influence manuscript submission (their employee, Mr Myklebust, could have withdrawn as an author). Except as stated herein, the sponsors played no role in the design and conduct of the study, in the collection, analysis, and interpretation of the data, or in the preparation, review, or approval of the manuscript.

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