Attitudes and Willingness of Laypersons Towards Applying Basic Life Support in Real Cardiac Arrest Situations: Prospective Observational Multi-Centre Study (LayResus 2023)

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Study registration: International Traditional Medicine Clinical Trial Registry (ISRCTNregistry) in progress

Background and Rationale

Ischaemic heart disease resulting in sudden cardiac arrest is the leading cause of death worldwide.[1] Early start of effective uninterrupted Basic Life Support (BLS) involving Cardiopulmonary Resuscitation (CPR) with Automated External Defibrillation (AED) doubles the survival from out-of-hospital cardiac arrest (OHCA).[1 2] This is based on high resource settings, which could still be applicable in low resource settings as well although no data available to support or deny this notation. The 2021 Consensus of Science and Treatment Recommendation (CoSTR) of the International Liaison Committee on Resuscitation (ILCOR) and the 2021 guidelines of the European Resuscitation Council (ERC) stressed the important role of the trained bystanders or laypersons in initiating early CPR in OHCA situations.[3 4] CPR should be started immediately in any unresponsive person with absent or abnormal breathing.[5] Failure to recognise cardiac arrest remains a missing key element in the chain of survival that could prevent the immediate start of CPR when needed and saving more lives. The implementation of frequent BLS training that enables as many people as possible to quickly identify OHCA, call for help, perform high-quality CPR and initiate early defibrillation is crucial for improvement of OHCA survival.[3]

Training of laypersons on BLS is established in many countries using different training modalities.[6 7] These have mainly focused on achieving the needed performance competencies, such as timely Emergency Medical Services (EMS) activation, effective chest compression, and AED utilisation to perform effective resuscitation when required.[8] The different training modalities for laypersons have focused mainly on achieving the needed competency to perform resuscitation when required. No differences in terms of performance competencies were identified between instructor-led and self-directed BLS adult training approaches.[9] While great emphases are invested on performance competencies during training, it is additionally

important for laypersons to learn the recognition of cardiac arrest which includes an unresponsive person with absent, agonal or abnormal breathing.

The 2021 ERC guidelines on Education identified enhancing willingness to perform CPR by laypersons as one of five key points in resuscitation education for laypersons and first responders.[10] Growing evidence shows that decreased willingness to start CPR by laypersons as an additional factor that hinders immediate resuscitation in OHCA situations.[1,2] Some factors, such as age and level of education of the laypersons, relationship with the cardiac arrest victim, and fear of causing more harm to the victim, were reported to alter the degree of willingness by laypersons to start resuscitation in OHCA situations.[3,4] However, investigating willingness to perform CPR in middle and low-resource settings is underreported in the literature. The need to investigate willingness and possible influencing factors, like religious and/ or cultural factors affecting willingness in such areas is going to help addressing the issue further in the form of training adjustment which might increase confidence in performing resuscitation when needed. The ILCOR 2020 CoSTR, stated that lay rescuers can use AED when providing CPR for OHCA as the evidence on damage or harm from accidental shock during resuscitation is minimal.[13] While this recommendation might convince some laypersons to help and might increase willingness to perform CPR, the lack of local Good Samaritan Law remains an issue to be addressed by society. The United Arab of Emirates is the only country in the Middle East to pass a Good Samaritan Law on November 2020, but we do not know if that changes the attitudes of the population to deliver CPR in OHCA.[14]

Aims of the Study:

The aims of this study are to:

Investigate the attitudes of laypersons towards BLS training

Study the willingness of laypersons to apply their learned resuscitation skills in real cardiac arrest situations

Identify possible barriers and enablers that might hinder or improve willingness of laypersons to apply their learned resuscitation skills after CPR training, if any.

Study Objectives:

The primary study objective is to investigate laypersons willingness to perform resuscitation in real cardiac arrest situations in order to further improve the outcome of OHCA.

Secondary study objective is to build local scientific evidence on the possible reasons of lack of willingness to perform resuscitation by laypersons which could be used to encourage local stakeholders and lawmakers to support resuscitation training and practice through community involvement in the public wellbeing.

Design and Methods:

Study Design: This is a multicentre crossectional questionnaire study on laypersons.

Study population: All study participants will be adult laypersons of both genders, aged eighteen and above, who were educated on any kind of resuscitation training either on CPR or BLS within the last 2 years in the involved countries.

Recruitment procedure: Participants will be recruited by direct contact of all, but not limited to, public volunteers who participated in the "World Restart A Heart (WRAH)" campaign in addition to all other national campaigns on resuscitation from the local organisers of these campaigns in the participating countries. Local participating institutes will contact these participants and obtain their approval to participate in the study after signing the informed consent manually or electronically.

Anonymity and ethics consideration: Participation in the study is voluntary. A written/ digital online informed consent will be obtained from each participant prior to inclusion. In all cases, all participating centres must submit the study to the local Institutional Review Board (IRB) or Ethics Committee for ethical judgment and obtain document of proof that the trial has been subject to ethical review and given approval by such committees. This process should take place prior to initiation of the study and in compliance with the applicable national regulatory requirement(s). This research project will be conducted in accordance with the Declaration of Helsinki protocol.[1] The project lead investigator with the national lead investigators in each participating centre acknowledge their responsibility as both overall project leader and national sponsors.

Inclusion and exclusion criteria: All eligible participants as mentioned above will be included. Exclusion criteria include children up to 18, not giving informed consent to participate, Language issues and inability to follow the study procedures.

Study questionnaire: The questionnaire will be composed of five sections (Appendix A):

a) *Demographic information* about the participants' age, gender, city and country of residence, level of education, occupation and socio-economic status in the form of open response questions.

Level of participants' CPR and AED knowledge utilising the 5 top messages on BLS according to the 2021 ERC Guidelines,

b) *Level of participants' CPR and AED knowledge* utilising the 5 top messages on BLS according to the 2021 BLS guidelines.[3] This will cover early signs of cardiac arrest, victim safety position, number to call the EMS, place of the palm on the victim thorax, appropriate depth, chest compression rate, and ratio of compression to rescue breaths, in the form multiple choice questions.

c) *Willingness* of the participant to help in real life OHCA situations, the 5-points Likert scale questions. on the following: (1) willingness to help in real life OHCA, (2) participation in local/ national neighbourhood resuscitation response teams, (3) willingness to attend CPR-training programs, (4) willingness of the inclusion in a national resuscitator registry, and (5) willingness to be part of the local/ national network of EMS as a first responder to OHCA.

d) *Possible barriers* for attending CPR training, and for applying resuscitation by the participant, and how it could be overcome. Closed set of questions on possible barriers for attending CPR training and for applying resuscitation in real OHCA situations.

e) *Possible enablers* that might help study participants to attend CPR-training. A closed set of questions on possible enablers that might help them in attending CPR-training, enable or facilitate them to help persons in cardiac arrest, or facilitate collaborating in local/ national lay rescuer organizations like first responders of advanced rescue teams.

Open response questions will be added as appropriate to allow participants to share their ideas/ concerns or suggestions.

Data processing and analysis: Data will be collected utilising an electronic questionnaire prepared as a Google form with a link on a mobile or tablet device that will be handed to the participant with direct supervision from one of the local investigators only to ensure appropriate operation of the device and the electronic questionnaire. The questions will be provided in two languages Arabic is the main language in addition to English or French as both represent a second language for some of the participating countries. All data entries will directly be pooled into a unified central database under direct control of the lead investigator as anonymous entries with only the name of the local investigator related to each entry to identify source and responsibility of data weaknesses or gaps to be completed.

Data collected in the unified central database will be reviewed by two independent researchers to ensure complete data entries. Any missing or incomplete data will be noted and excluded from the database.

Cronbach's alpha will be used to measure the internal consistency of the knowledge section questions. A cumulative knowledge score will then be calculated by adding +1 for each correct answer or positive attitude/ willingness answer and a 0 for wrong, missing or negative attitude/ willingness answer to the sum score which will be converted to a percentage of the expected total positive score. Continuous variables will be expressed in the form of mean ± standard deviation (SD) and will be preliminarily tested for normal distribution.

Categorical data will be reported as percent values, univariate comparison between different proportions will be evaluated through Chi-squared test as willingness to apply resuscitation with demographic data. Variables with p-value less than 0.05 are then included in a logistic regression model to determine the factors associated with willingness to apply resuscitation and the possible barriers. The results will then be expressed as multivariate Odds Ratio (mOR) and 95% confidence interval (CI). Significance level for all analyses will be set for $p < 0.05$.

Secondary outcome analysis per country will also be included to compare the degree between the participating countries in laypersons' willingness and readiness to engage in real OHCA resuscitation situations.

Data handling and record keeping / archiving: Access to the unified central database will be granted only to the lead investigator and the two independent researches. Data sheet will be protected by a personalized and confidential password. No names, participant initials or local center numbers will be collected or kept on the data acquisition forms, nor electronically. Each center will maintain an lead local investigator file including: protocol, IRB approval document, local investigator delegation log and a hard copy of the informed consent form with translation from Arabic to English/ French as applicable.

Participants' information and informed consent: The participants will be presented with the IRB approved electronic Participant Information Sheet translated as appropriate to make an informed decision about their participation in the study, i.e. explaining the nature of the study, its purpose, the expected duration, the potential risks and benefits (Appendix 2). Each participant will be informed that their participation in the study is voluntary and that he/ she may request to withdraw their filled questionnaire from the study at any time and without explanation. Participants will confirm that they were given adequate time to reach a decision. The participant will be given the option to receive an electronic copy of his/ her filled questionnaire by e-mail upon request and provision of his/ her e-mail.

Participants' privacy: The investigator affirms and upholds the principle of the participants' right to privacy and shall comply with applicable privacy laws. Specifically, anonymity of the participants shall be guaranteed when presenting the data at scientific meetings or publishing them in scientific journals. Individual subject personal information obtained as a result of this study is considered confidential and disclosure to third parties is prohibited. Subject confidentiality will be further ensured by utilising subject identification code numbers and only research question data will be present in the unified central database. For data verification purposes, authorised representatives of the sponsor or an ethics committee may require direct access to parts of the participant's personal records relevant to the study.

Confidentiality, Data Protection: To safeguard participants' confidentiality, a participant's identification code will be assigned automatically to encode data by in the electronic central database upon filling the questionnaire. The confidential log linking participant identification code and identifiable participant data will be stored separately by the local lead investigator in a secured electronic format and will be protected by personalised and confidential usernames and passwords. Further, only encrypted data will be stored centrally.

Why is this study of importance? Studying the willingness of laypersons to apply their learned performance competences in real cardiac arrest situations and identifying possible barriers that need to be addressed to improve willingness by building ideas, tools and approaches to address that during training and awareness campaigns to improve willingness. This collected evidence in turn would also help in building up a regional and national consensus to encourage stakeholders and lawmakers to support resuscitation training and practice through middle and low-income communities.

There is a clear diffusion in practice across the world to address the attitudes and willingness of laypersons in performing CPR in real OHCA situations. Because our literature research found a lack of evidence in the literature for middle and low-income communities about that topic. With this low costs study we aim to answer some of the important questions at the earlies time in the rescue process of a cardiac arrest victim: the recognition of a life-threatening event. Without that guidelines or best practice resuscitation care will not be applied and all the training on CPR is for nothing. We intend, by performing a large, international, multicentre study investigating attitudes and willingness of laypersons in performing CPR in real OHCA situations, to determine as outcomes a list of factors affect willingness to help of laypersons and to develop an action plan to address these factors. Furthermore, we aim to utilize the identified factors and the developed action plan to initiate and push for Good Samaritan Laws in the different countries and to get local national support to the involvement laypersons in resuscitation. The collaboration among the national Resuscitation Councils will ensure the quality, documentation, verification and follow-up of the entire study.

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