University of Applied Sciences and Arts Northwestern Switzerland
School of Life Sciences

Clinical Decision Support System (CDSS)

Paediatric Life Support

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1. Introduction

The primary objective of the Clinical Decision Support System (CDSS) is to provide a system that facilitates paediatric advanced life support, focusing on the management of critically ill infants and children up to 18 years old. The CDSS is specifically designed for care before, during, and after cardiac arrest, with the *European Resuscitation Council Guideline: Paediatric advanced life support:* *https://cprguidelines.eu/assets/guidelines/European-Resuscitation-Council-Guidelines-2021-Pa.pdf* serving as the basis for its development.

The CDSS presents an updated set of recommendations for paediatric life support, incorporating the latest evidence and expert consensus. This includes the recognition and management of critically ill children, paediatric basic life support, paediatric advanced life support, and post-resuscitation care. However, to avoid overwhelming complexity, the developed CDSS is limited to paediatric advanced life support (PALS).

The main objective of the developed CDSS is to assist in the decision-making process for shockable and non-shockable heart rhythms (Paediatric Advanced Life Support), as well as manage chest compressions, drug doses, and shock dosages. Although the sequence of actions is presented step-by-step in the CDSS, advanced life support (ALS) is a team activity, and several interventions will be done in parallel. ALS teams should not only train in knowledge and skills but also in teamwork and the 'choreography' of ALS interventions.

It is essential to recognize that critical illness in children and infants involves distinct aetiologies and pathophysiological processes compared to adults. While the developed CDSS offers significant advancements in paediatric critical care situations and training for paediatricians, it is important to acknowledge the inherent limitations of applying the CDSS and guidelines universally across different contexts.

2. Operational (L2)

2.1. Component 1: Health interventions and recommendations

The European Resuscitation Council Guidelines 2021: Paediatric Life Support provides a comprehensive framework for managing critically ill or injured children. The main objectives and key points are summarized here structured on the main chapters *Recognition and Management of Critically Children, PBLS (Basic Life Support), PALS (Advanced Life Support), Oxygenation and Ventilation, Post-Resuscitation Care***.**

The focus in this summary is particularly on Paediatric Advanced Life support (PALS), as this is the area where the developed CDSS system operates.

Recognition and Management of Critically Children:

- Use the Paediatric Assessment Triangle for early recognition.
- Follow the ABCDE approach for assessment:
  - **A**irway: Ensure patency.
  - **B**reathing: Check respiratory rate, work of breathing, tidal volume, and oxygenation.
  - **C**irculation: Evaluate pulse rate, pulse volume, peripheral circulation, blood pressure, and preload.
  - **D**isability: Assess consciousness using AVPU or Glasgow Coma Scale.
  - **E**xposure: Fully expose the child to identify any hidden injuries or signs of illness .

Paediatric Basic Life Support (PBLS):

- Use the specific PBLS algorithm for anyone trained.
- After the initial 5 rescue breaths, proceed with chest compressions unless there are clear signs of circulation.
- Single rescuers should call for help (using speakerphone) and perform CPR for 1 minute before seeking further help if alone.
- Use a two-thumb encircling technique for infant chest compressions by a single rescuer.

Paediatric Advanced Life Support (PALS):

PALS is a team-based approach where multiple interventions often occur simultaneously. The sequence is presented in a stepwise manner for clarity, but teamwork and coordination are crucial for effective resuscitation.

1. **Recognition and Management of Cardiac Arrest:**

Immediate Actions:

- **Commence and continue with Paediatric Basic Life Support (PBLS):** This includes high-quality CPR if the child is bradycardic with signs of poor perfusion despite adequate respiratory support.
- **Apply Cardiac Monitoring:** As soon as possible, attach ECG electrodes or self-adhesive defibrillator pads to differentiate between shockable and non-shockable rhythms.

Cardiac Rhythm Management:

- **Shockable Rhythms:** If a shockable rhythm (e.g., ventricular fibrillation or pulseless ventricular tachycardia) is identified, deliver a shock as per defibrillation protocols.
- **Non-Shockable Rhythms:** These include pulseless electrical activity (PEA), bradycardia, and asystole. For bradycardia with a pulse rate less than 60 beats per minute and poor perfusion, initiate CPR even if a pulse is present.

CPR and Drug Administration:

- **High-Quality CPR:** Continue uninterrupted CPR unless signs of life are observed. Emphasize consistent, high-quality compressions and ventilations.
- **Adrenaline Administration:** Obtain vascular access (preferably IV, otherwise IO) and administer adrenaline (10 mcg/kg, max 1 mg) as soon as possible, repeating every 3-5 minutes.

Oxygenation, Ventilation and Advanced Airway Management:

- Avoid hyperventilation and ensure adequate lung inflation during chest compressions.
- **Bag-Mask Ventilation (BMV):** Preferably performed by two providers. For intubated patients, provide asynchronous ventilation at an age-appropriate rate (10-25 breaths per minute).
- **Endotracheal Intubation:** Consider if BMV is ineffective or prolonged respiratory support is anticipated. Confirm placement with capnography and secure the tube properly.

Identify and Treat Reversible Causes:

- Actively search for and treat potential reversible causes of cardiac arrest, often summarized by the "4 Hs and 4 Ts":

- Hypoxia, Hypovolemia, Hypo/hyperkalemia, Hypothermia
- Tension pneumothorax, Tamponade (cardiac), Toxins, Thromboembolism (pulmonary or coronary)

2. **Post-Resuscitation Care:**
    - **Continuous Monitoring:** Ensure continuous ECG, blood pressure, and oxygen saturation monitoring.
    - **Supportive Care:** Maintain normothermia, normoglycemia, and adequate ventilation. Provide ongoing assessment and management of organ perfusion and function.
    - **Treatment of underlying causes:** Address and manage underlying causes or proceed with an in-depth investigation to uncover additional contributing factors.
3. **Team Coordination:**
    - Effective resuscitation relies on clear communication, task delegation, and closed-loop communication. Ensure all team members are aware of their roles and responsibilities during the resuscitation process.

2.1.1 Challenges of translation from L1 to L2

The guideline contains various interdependent directives. To develop a usable and accepted CDSS for the target audience, it is essential to identify the corresponding important sections and present them at the appropriate time. Given that this is a team process with parallel elements, representing it adequately in a BPMN (Business Process Model and Notation) is challenging. Additionally, although there are indications for the importance of regular reviews of certain subprocesses, balancing the necessity of reassessment with sufficient intervals to avoid alert fatigue is challenging. This aspect must be graphically considered and skillfully processed in future representations. Moreover, legal differences across countries must be considered. To achieve a clear representation of a very complex team process, the determination and breakdown of subprocesses in BPMN coding, along with the repetitive cycles of certain sections with different partly quantity-dependent sub-paths, was extensive and challenging.

2.2. Component 2: Generic personas

In the context of Paediatric Advanced Life Support the following personas have direct or indirect impact on the process. In figure 1 is an overview of personas involved.

2.2.1 Targeted generic personas

The targeted personas for this PALS CDSS are resuscitation teams, primary healthcare providers/paediatrics and emergency department physicians:

- **Resuscitation teams:** Resuscitation teams are specialized groups of healthcare professionals trained to provide immediate and advanced life-saving interventions. These teams typically include doctors, nurses, paramedics, and other healthcare workers. They are trained in rapid responses to various conditions, effective resuscitation techniques, and post-resuscitation care to improve patient survival rates.
- **Emergency department physicians:** Doctors specializing in immediate decision-making and treatment of critically ill people.
- **Primary healthcare providers/paediatrics:** Primary healthcare providers in paediatrics are medical professionals specialized in delivering comprehensive, first-line healthcare services to infants, children, and adolescents.

2.2.2 Related personas

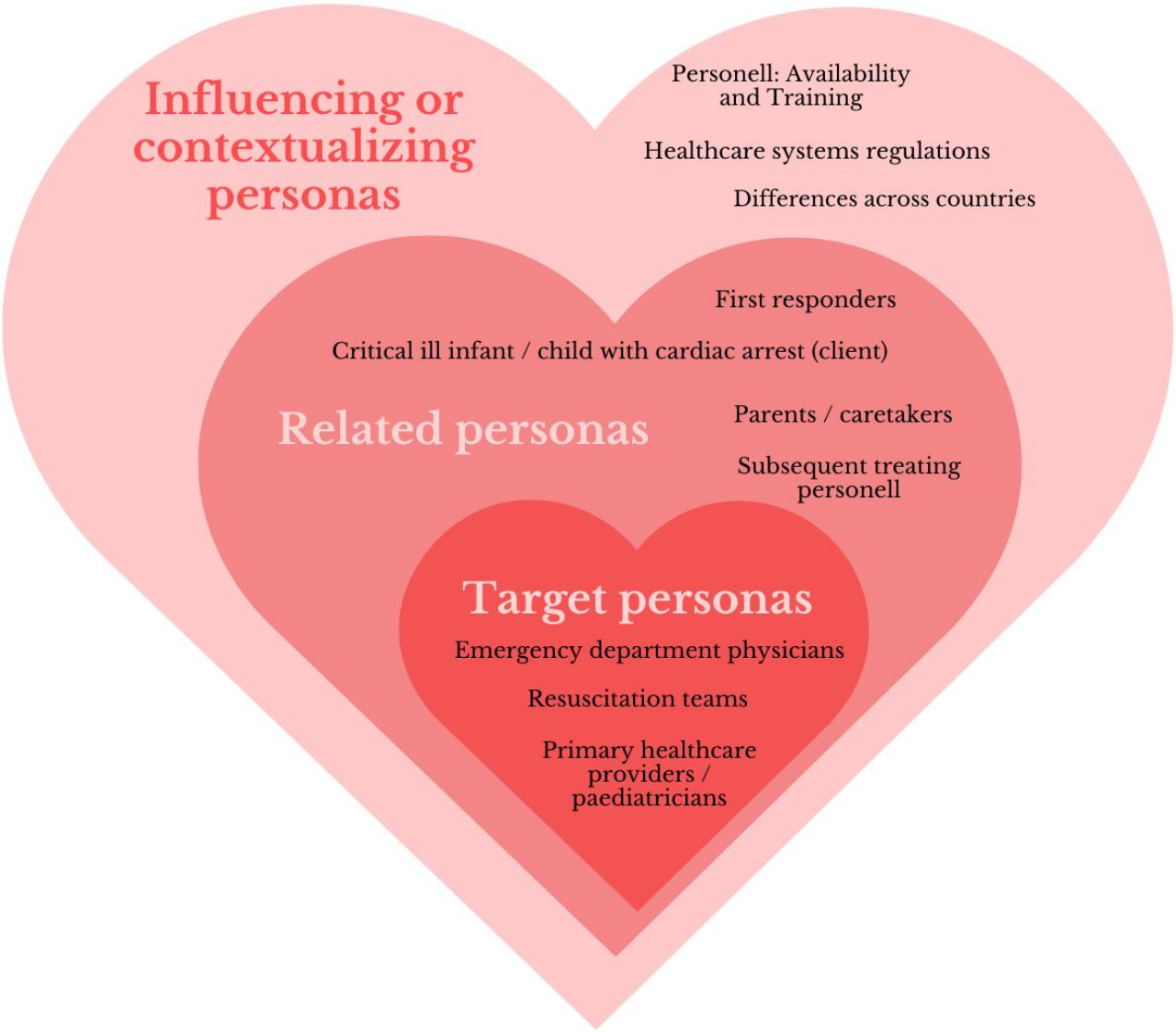
Other important personas involved are PALS trained emergency paramedics and nursing staff. However, since this is a support system and important decisions including medication dosage are involved, they are not the primary targeted personas.

Additional personas related are:

- Critical ill infant/child with cardiac arrest (client): These are the primary clients to receive PALS due to various reasons including but not limited to drowning, trauma, sepsis, pre-known serious conditions/illnesses. They expect a guideline driven treatment of cardiac arrest taking into account their age and age-related special characteristics.
- First responder: The person that recognizes the critical ill status of the client and initiate first aid and get help. This could be any person.
- Parents/caretakers: The parents/caretakers of the infant/child may have important information facilitating for or restriction of treatment.
- Further treating personal: Including surgeons, intensive care personal may be needed for highly specialized treatments within the PALS or after PALS.

2.2.3 Additional considerations for contextualizing personas

This PALS CDSS is based on the European Resuscitation Council (ERC) Guidelines 2021. There may be differences in certain countries and health systems including regulations of healthcare personnel.



2.3. Component 3: User scenarios

User Scenario 1: Paediatric cardiac arrest in the emergency room

Key Personas:

- Patient: Sam
- Family, father: Ben
- Team Leader: Dr. Katy, Paediatric Emergency Physician
- Nurse: Cynthia, Paediatric Nurse
- Respiratory Therapist: Jack
- Paramedic: Thomas

Scenario:

A 6-year-old child, Sam, is brought into the emergency room by paramedic Thomas after collapsing at home. Thomas reports that Sam was found unresponsive and not breathing by his father Ben. Immediate Basic Life Support (BLS) was initiated by Ben and continued by Thomas during transport.

Upon arrival, Dr. Katy takes charge as the team leader. Cynthia begins chest compressions while Jack sets up the bag-mask ventilation with 100% oxygen. Alex applies self-adhesive defibrillator pads and connects them to the cardiac monitor.

Dr. Katy uses the digital assist system to guide the team through the PALS protocol, entering his estimated weigth of 20 kg. The system prompts her to assess Sam's cardiac rhythm. The cardiac monitor shows pulseless electrical activity (PEA). The system displays a checklist for managing PEA, including continuing high-quality CPR, which Dr. Katy instructs her team to do, while she assesses for signs of life and possible reversible causes.

Cynthia continues compressions without pausing to check the pulse, following the guidance from the digital assist system. Dr. Katy requests vascular access, and the system suggests options for difficult IV access, including intraosseous (IO) access. As Dr. Katy is unable to secure an IV line quickly, she instructs Thomas to establish intraosseous (IO) access. Once access is achieved, Cynthia administers the first dose of 200 mcg adrenaline (10 mcg/kg) and flushes it with saline, as calculated and displayed by the digital assist system.

The system sets a timer and reminds the team to reassess the cardiac rhythm after 2 minutes. The monitor still shows PEA. Prompted by the system, Dr. Katy instructs the team to continue CPR and prepare for the next dose of adrenaline.

User Scenario 2: Paediatric ventricular fibrillation in a paediatric intensive care unit

Key Personas:

- Patient: Maya
- PICA Attending: Dr. Patrick
- PICU Nurse: Lea
- PICU Fellow: Dr. Astrid
- Respiratory Therapist: Mick

Scenario:

An 8-year-old girl, Maya, in the PICU following surgery for congenital heart disease suddenly goes into cardiac arrest. The bedside monitor alarms, showing ventricular fibrillation (VF).

Lea immediately starts chest compressions and calls for help. Dr. Patrick, Dr. Astrid, and Mick rush to the bedside. Mick takes over ventilation with a bag-mask and 100% oxygen. Dr. Astrid prepares the defibrillator and attaches self-adhesive pads to Maya's chest.

Dr. Patrick uses the digital assist system to follow the PALS protocol for VF. Maya's weight of 26 kg has been entered, and the system prompts him to charge the defibrillator to 104 J (4 J/kg) and displays instructions to ensure all rescuers are clear of the patient before delivering the shock.

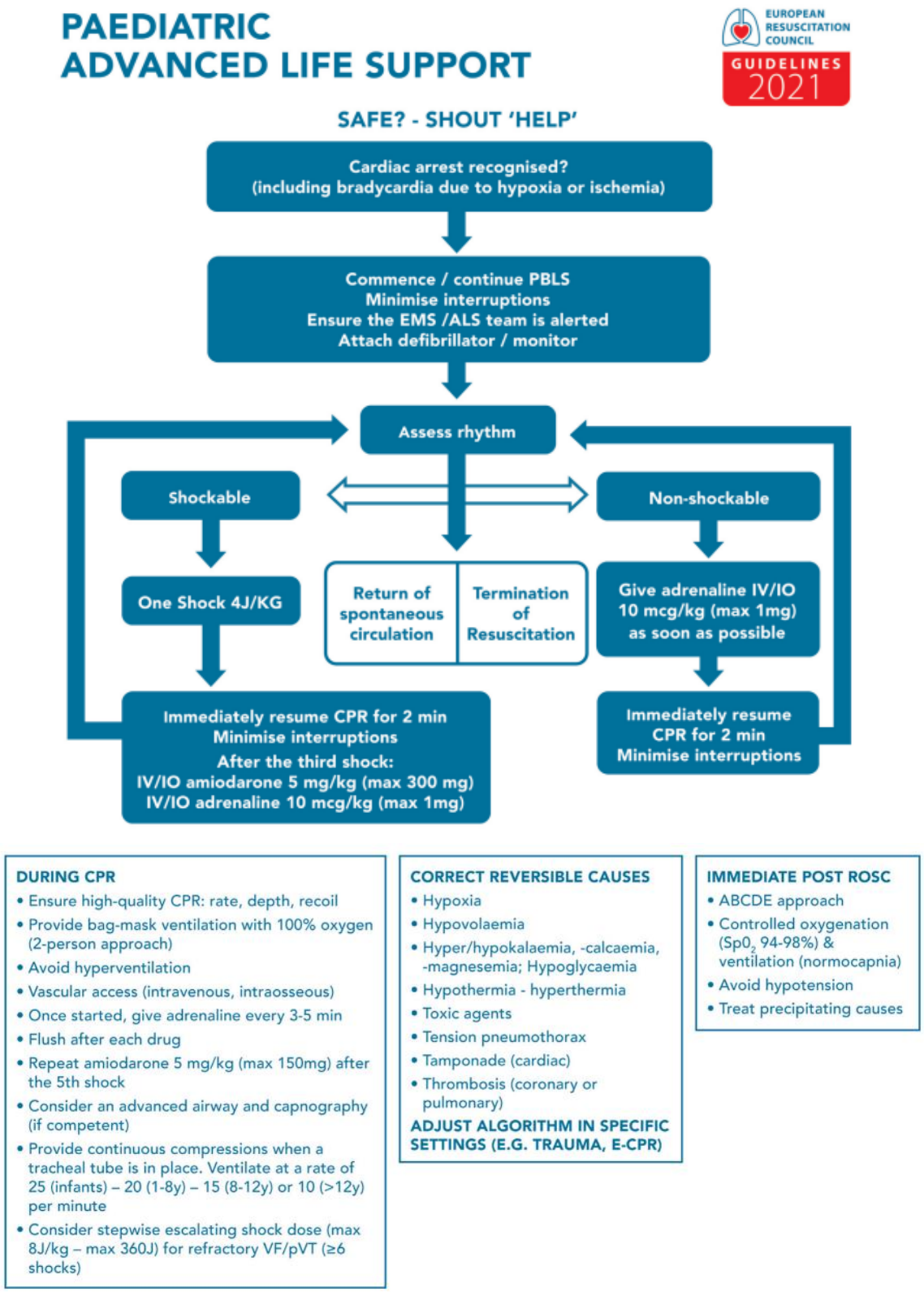
Dr. Astrid charges the defibrilator, and the digital assist system counts down to minimize the delay between stopping chest compressions and delivering the shock. Once charged, compressions are paused, and Dr. Astrid delivers the shock. The system immediately prompts the team to resume CPR.

After 2 minutes, the digital assist system alerts Dr. Patrick to reassess the rhythm. The rhythm still shows persistent VF. The system advises administering 260 mcg adrenaline (10 mcg/kg) and 130 mg amiodarone (5 mg/kg), followed by a saline flush. The team follows these prompts, preparing for another shock.

After the third shock, Maya's rhythm changes to an organized rhythm, and spontaneaous circulation returns (ROSC) as indicated by improved etCO2 levels and spontaneaous breathing. The digital assist system provides post-ROSC care guidelines, advising the team to titrate oxygen to maintain SpO2 between 94-98% and to closely monitor Maya's vital signs.

2.4. Component 4: Generic business process and workflows

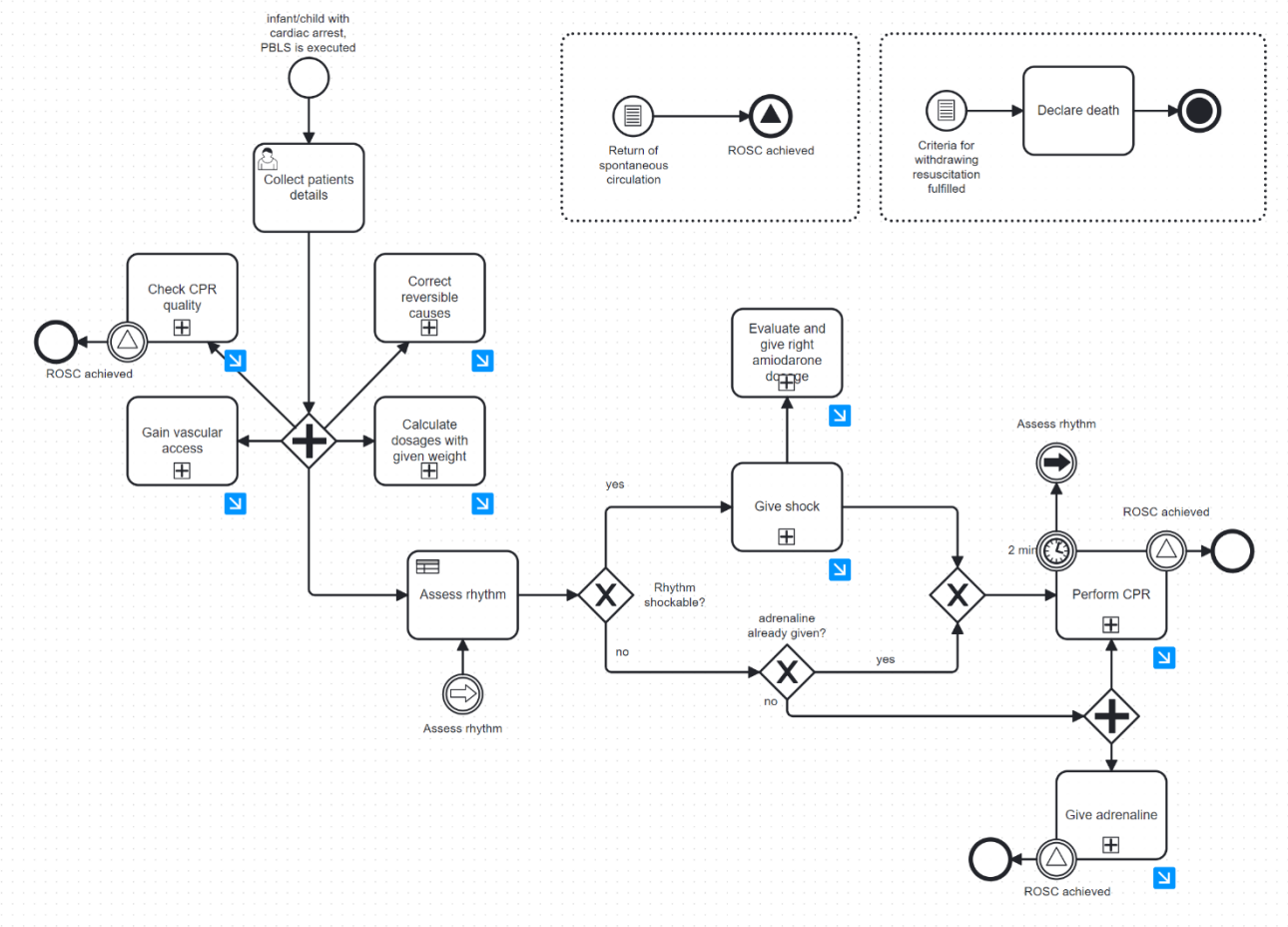
Based on the diagram of the European Resuscitation Council guidelines the following diagram is translated into a more machine readable BPMN standard.



2.4.1 Overview of the key processes

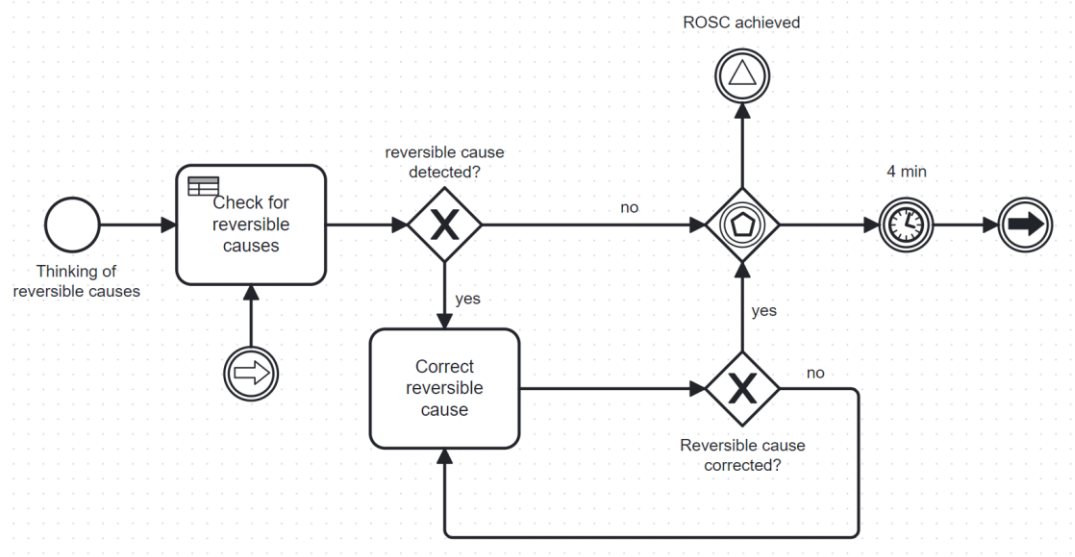
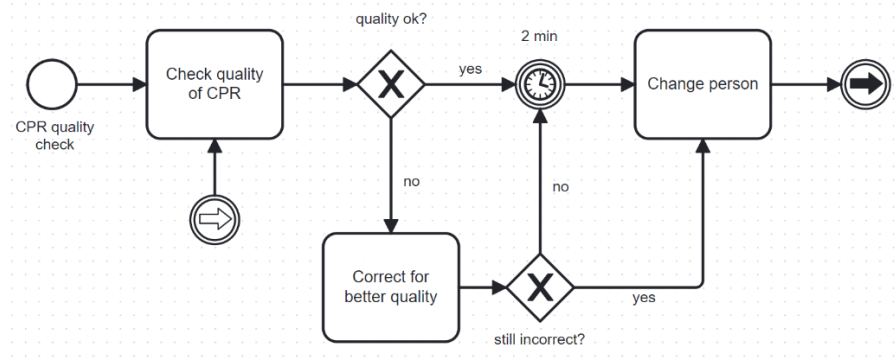
The following diagram shows the key process of PALS. As PALS is executed by a team, orchestrated by a team-leader, there are several sub-processes and loops taking place in parallel.

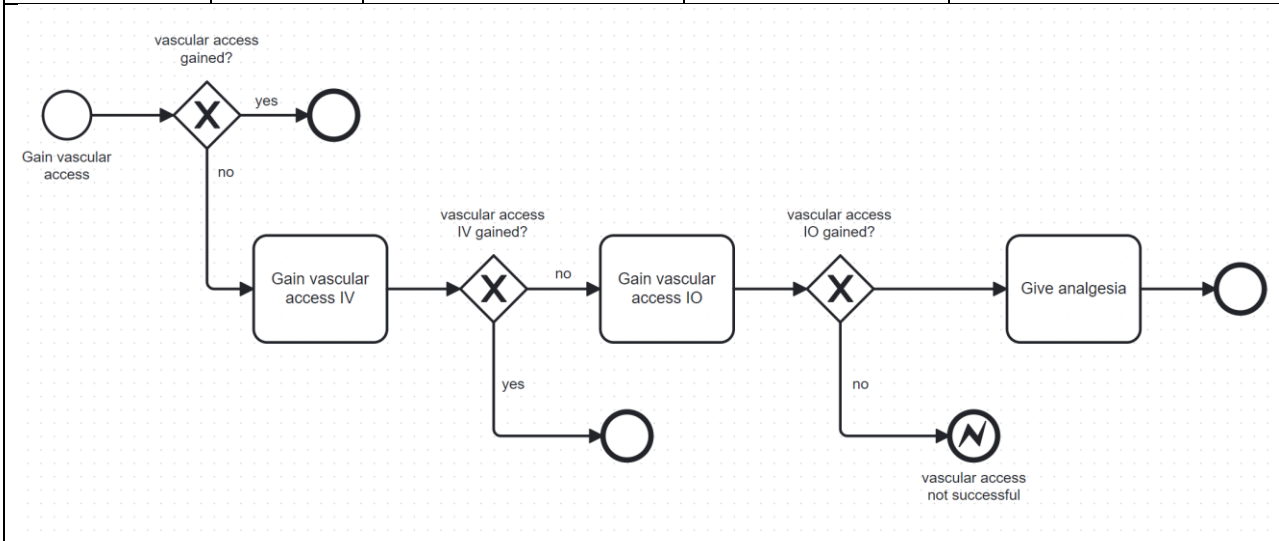
The workflows are structured using standardized notations for business process models (BPMN).

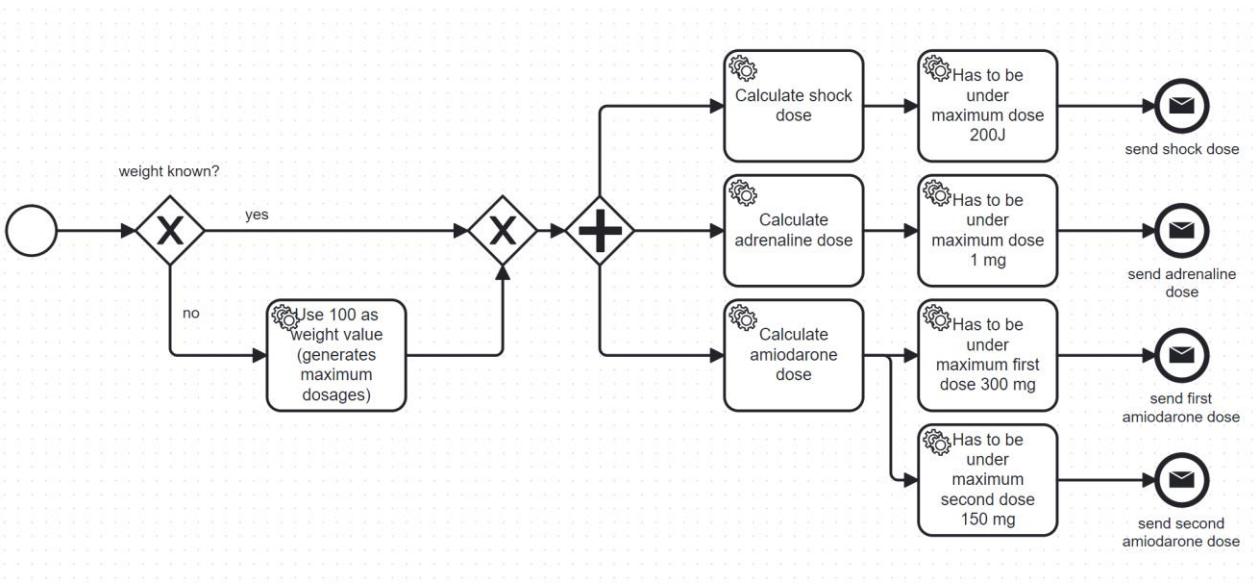


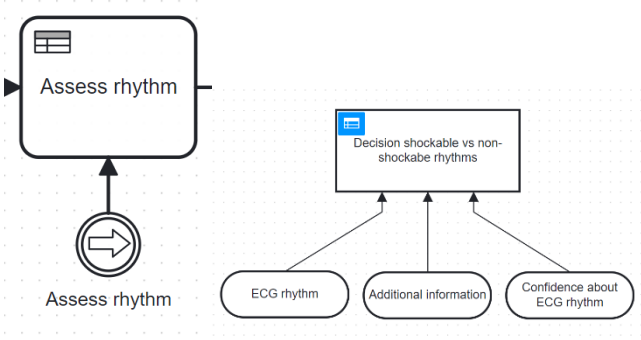
The table below outlines the critical components of the PALS workflow, detailing each key sub-process.

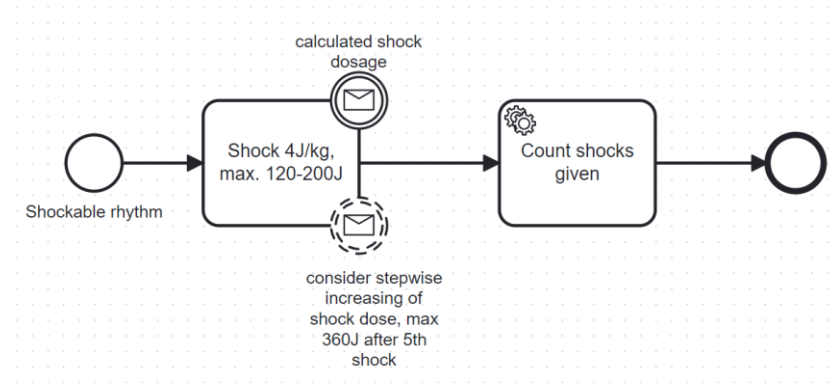
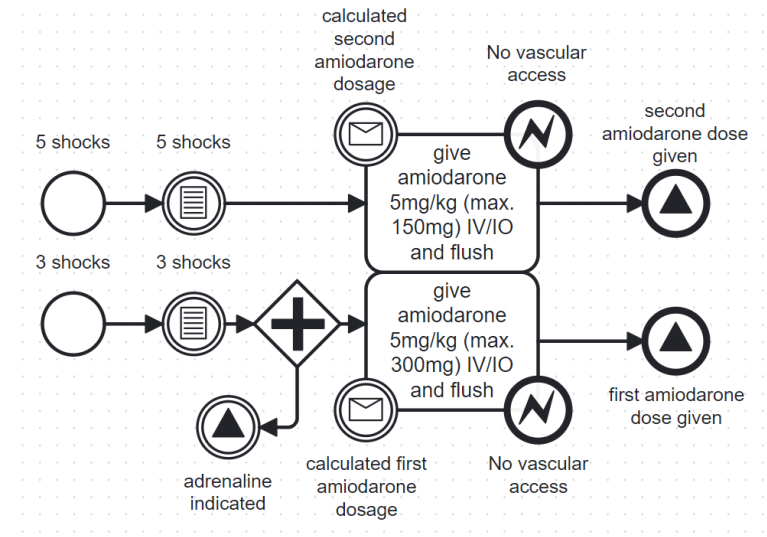
Process Name	Process ID	Personas	Objective	Task set
Correct reversible causes	PALS.01	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or	Identify possible reversible causes of cardiac arrest of the infant/child	There are frequent reversible causes listed in a decision table which the leading person must check for. If a reason is identified this should be addressed. This should

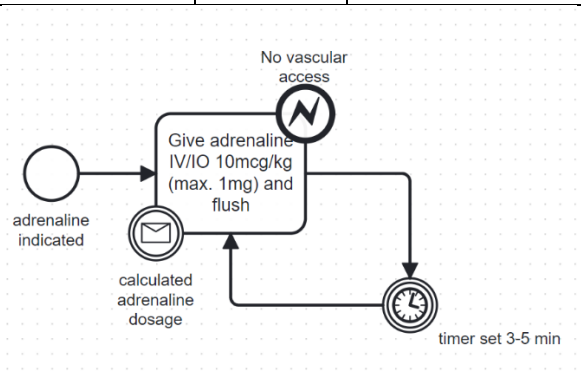
		-primary healthcare providers/paediatric		be checked every 4 min. till return of spontaneous circulation (ROSC) is achieved.
				
Check CPR quality	PALS.02	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	Assure that CPR is performed appropriately and well.	If deficits in CPR performance are identified this should be addressed. Frequent changes of executing persons should be made to avoid exhaustion. This sub-process is a loop with timed reassessment and will be stopped if ROSC was achieved.
				

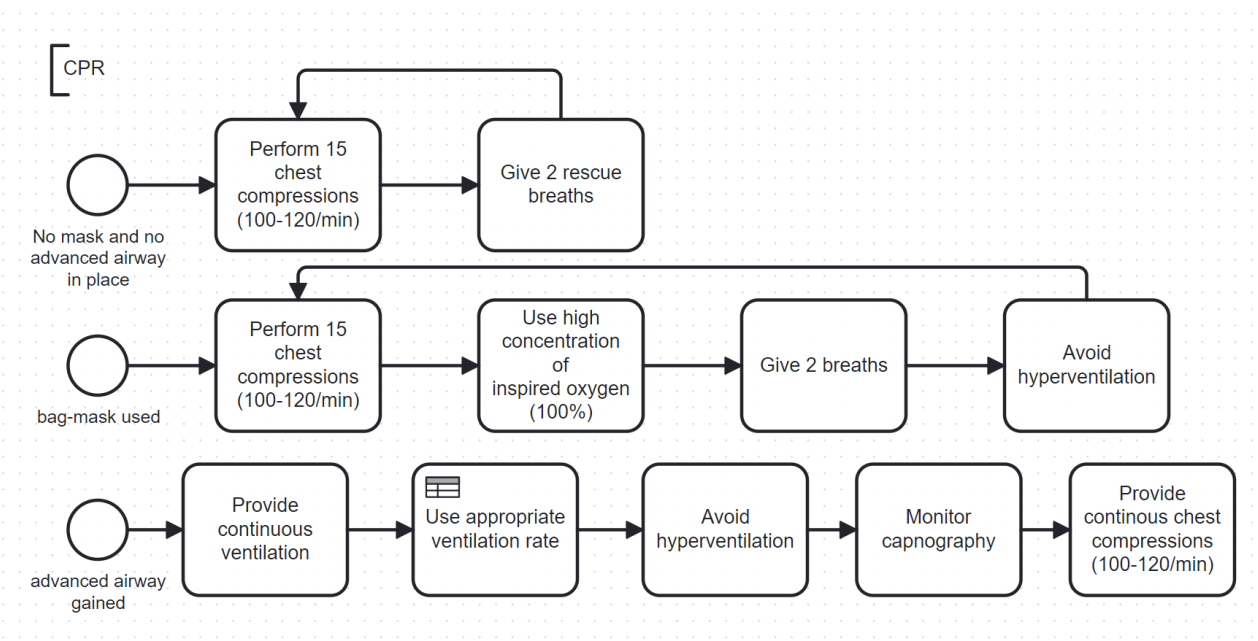
Gain vascular access	PALS.03	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	This should guide to gain sufficient vascular access for upcoming administration of medication.	For upcoming steps, it is crucial to have access to the vascular system. If an IV access is not possible there should be other possibilities considered.
				
Calculate dosages with given weight	PALS.04	-automated	It is important to calculate medication and shock dosages according to the given weight and not exceed the recommended maximum dosage.	By means of the weight automated calculations are made and sent to the according tasks. If weight is not known, this will calculate the maximum dosages. It is not possible to exceed the maximum dosages.



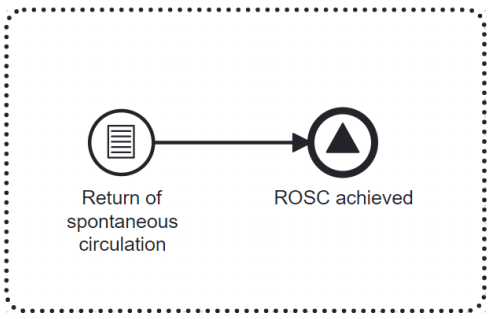
Assess rhythm	PALS.05	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	To assess the rhythm and decide whether it is shockable or not.	The heart rhythm is assessed and a decision table indicates if a shock should be given or not. If in doubt, the decision table will indicate to give a shock.
				
Give shock	PALS.06	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or	Facilitating the estimation of shock dosage, dosage raise and counts of shocks given.	After the decision was made to give a shock, this sub-process will indicate the calculated dosage for the shock. Shocks given are counted and reminder to

		-primary healthcare providers / paediatric		evaluate dosage raise for the next shock is set.
				
Evaluate and give right amiodarone dosage	PALS.07	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	There are certain recommended dosages for amiodarone administration in after 3rd and 5th shock. Additionally, adrenaline should be given, if not done yet.	There is a reminder and guidance to amiodarone administration after 3rd and 5th shock showing calculated (or maximum) dosage according to the guideline. Additionally, adrenaline administration should be started, if not done, yet. If no vascular access could be gained, this step will be canceled.
				

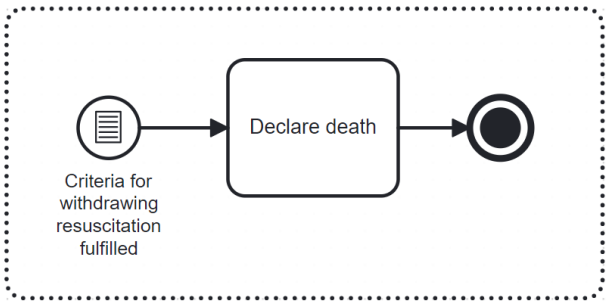
Give adrenaline	PALS.08	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	Administration of adrenaline is recommended for non-shockable cardiac arrests and every 4 min. after it has been started.	This ensures the immediate administration of adrenaline if non-shockable cardiac arrest is detected. It includes a 4 min.-timer to remind of its recurring administration. This sub-process will be stopped if ROSC was achieved.
				
Perform CPR	PALS.09	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	Performance of CPR is dependent of ventilation type used and follows a certain ventilation frequency and chest compression rate.	Depending on the ventilation type it is guided throw the correct performance of CPR according to the infant's/child's age showing correct ventilation rates and chest compression rates. After two minutes a timer will indicate to go back to "Assess rhythm". This subprocess will be stopped if ROSC was achieved.



Return of spontaneous circulation	PALS.10	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or -primary healthcare providers/paediatric	Possibility to indicate ROSC.	By indicating that ROSC was achieved, this will send a signal to certain sub-processes, that should be stopped.



Criteria for withdrawing resuscitation fulfilled	PALS.11	-Infant/child with cardiac arrest -Resuscitation team or -emergency department physician or	Ending the whole process if measures were unsuccessful.	By indication of withdrawal of resuscitation and declaration of death, the whole process will be stopped.

		-primary healthcare providers/paediatric		
				

2.5. Component 5: Core data elements

- This section outlines the core set of data elements corresponding to different points of the workflow within the identified business processes. These data elements provide the foundation for executing the decision-support logic, as well as populating indicators and performance metrics

Activity	Data element name	Type	Description & definition	Response options	Conditional logic
Gather client details	Unique identification	Text	Unique identifier for new clients or a universal ID, if used in the country		
	First name	Text	Childs first name		
	Last name	Text	Childs family name or last name		
	Contact date	Date	The date and time of the first contact		
	Date of birth (DOB)	Date	Childs DOB, if known		
	Age	Integer	Age		Based on DOB
	Weight	Decimal	Weight in kilograms		
	Emergency contact's name	Text	Name of an emergency contact, the mother		
Cardiac arrest	Cardiac arrest recognised?	Boolean	Recognition of cardiac arrest, including bradycardia due to hypoxia or ischemia	Yes / No	
	Vascular access IV gained?	Boolean		Yes / No	
	Vascular access IO gained?	Boolean		Yes / No	
Attach Machines	Defibrillator attached?	Boolean		Yes / No	
	Monitor attached?	Boolean		Yes / No	
Advanced	Assess heart rythm	Multiple	Assess heart rhythm	PVT,VF,PEA,	

Life Support				Bradycardia, Asystole	
	Shockable	Boolean	Information if rythm is shockable or non-shockable	Yes / No	Displayed if Assess heart rhythm results in PVT or VF.
	Shock-Dose	Decimal	If hearth rythm is shockable, the dosage of the shock		Displayed if Shockable is Yes, value based on weight and guideline
	Adrenaline-Dose	Decimal	The dose of adrenaline given		Derived based on weight and guideline
	Amiodarone-Dose	Decimal	The dose of amiodarone given		Derived based on weight and guideline
	Rounds	Integer	The number of rounds (shocked)		
	CPR	Integer	The amount of time to resume Chest compressions.		Timer based on guideline

2.6. Component 6: Decision-support logic

Decision-support logic and algorithms to support appropriate service delivery in accordance with WHO clinical, public health and data use guidelines.

Guideline: Shockable or non-shockable

Reference from the paper:

If not already in place, apply cardiac monitoring as soon as possible using ECG-electrodes or self-adhesive defibrillator pads (or defibrillation paddles). Differentiate between shockable and non-shockable cardiac rhythms.

***Non-shockable** rhythms are pulseless electrical activity (PEA), bradycardia and asystole. If bradycardia (<60 per minute) is the result of hypoxia or ischaemia, CPR is needed even if there is still a detectable pulse. Therefore, providers should rather assess signs of life and not lose time by checking for a pulse. In the absence of signs of life, continue to provide high- quality CPR. Obtain vascular access and give adrenaline IV (10 mcg/ kg, max 1 mg) as soon as possible. Flush afterwards to facilitate drug delivery. Repeat adrenaline every 35 min. In cases where it is likely to be difficult to obtain IV access, immediately go for IO access.*

Shockable rhythms** are pulseless ventricular tachycardia (pVT) and ventricular fibrillation (VF). As soon identified, defibrillation should immediately be attempted (regardless of the ECG amplitude). **If in doubt, consider the rhythm to be shockable.

Translated into:

- **Shockable**
  - **Pulseless Ventricular Tachycardia (pVT)**
    - This is a rapid, abnormal heart rhythm originating from the ventricles (lower chambers of the heart) that leads to ineffective pumping of blood. The heart beats very quickly but ineffectively, resulting in inadequate blood flow to the body.
  - **Ventricular Fibrillation (VF)**:
    - VF is a chaotic, disorganized electrical activity in the ventricles. Instead of contracting normally, the heart muscle quivers or fibrillates, preventing effective pumping of blood. VF is a leading cause of sudden cardiac arrest.

- **Non-shockable**
    - **Pulseless Electrical Activity (PEA)**
        - PEA occurs when the heart's electrical activity appears normal on an electrocardiogram (ECG), but there is no effective mechanical activity of the heart. In other words, there is no pulse despite the presence of electrical activity.
    - **Bradycardia**
        - This refers to an abnormally slow heart rate, usually defined as less than 60 beats per minute. While severe bradycardia can lead to cardiac arrest, it is typically not treated with defibrillation.
    - **Asystole**
        - Asystole is the absence of any electrical activity in the heart. It is often referred to as "flatline" and represents the most severe form of cardiac arrest.

Guideline: Assess heart Rythm

Guideline: Cardiac arrest recognised

https://www.heart.org/en/health-topics/cardiac-arrest/emergency-treatment-of-cardiac-arrest

What can be measured

- Capnography, Invasive blood pressure, point of care ultrasound, point of care serum values

2.7. Component 7: Indicators and performance metrics

The paediatric life support system incorporates a fundamental set of indicators and performance metrics that are critical for informed decision-making, monitoring clinical performance, and fulfilling

subnational and national reporting requirements. These indicators and metrics are derived from data captured through the routine digital system, ensuring real-time accuracy and relevance.

The core indicators encompass patient demographics, which gather age, weight, and other vital statistics of the patients to comprehend the population being treated and adjust interventions accordingly. For instance, this would encompass tracking the average age of patients and the distribution of their weights. Another essential indicator is cardiac arrest recognition and response times, which measures the swiftness and proficiency of recognizing cardiac arrest and initiating appropriate interventions. Metrics such as the time from cardiac arrest recognition to the first defibrillation and the time from recognition to the first administration of adrenaline are vital in this category. CPR quality metrics assess the quality of cardiopulmonary resuscitation performed, including compression rate and depth. This comprises average chest compression rates and the percentage of compressions meeting the depth standard. Defibrillation metrics supervise the effectiveness and frequency of defibrillation attempts, capturing data on the number of defibrillation shocks administered and the success rate of the first shock in achieving return of spontaneous circulation (ROSC).

Medication administration is a vital sign and tracks the administration of critical medications such as adrenaline and amiodarone, ensuring adherence to guidelines. Metrics include the doses of adrenaline administered and adherence to dosing intervals. Outcomes of interventions measure the immediate outcomes of life support interventions, including survival rates and ROSC, with data on ROSC rates and survival to hospital discharge being particularly important. Post-resuscitation care evaluates the quality and effectiveness of care provided to patients after resuscitation, monitoring the time to targeted temperature management and adherence to oxygen saturation targets post-ROSC. Training and competency metrics assess the training levels and competency of healthcare providers using the system, tracking the frequency of training sessions attended and scores on competency assessments.

Performance metrics include efficiency metrics, which measure the time efficiency of different steps in the paediatric life support protocol. Examples include the average time to complete the entire protocol and time saved using automated calculations and reminders. Compliance metrics assess adherence to clinical guidelines and protocols, measuring compliance rates with PALS guidelines and deviation rates from recommended protocols. Data quality metrics ensure the accuracy and completeness of data collected through the system, tracking the percentage of missing data fields and data entry error rates.

System utilization metrics monitor the usage and engagement levels of the digital system by healthcare providers, including the number of active users and the frequency of system access during emergencies. Patient outcome metrics measure the impact of the system on patient outcomes, such

as patient survival rates and long-term neurological outcomes of survivors. Operational metrics track the operational efficiency of the healthcare facility in managing paediatric emergencies, such as bed turnover rates in the intensive care unit and the average length of stay for resuscitated patients.

Further Information:

Paediatric basic life support Guidelines | Resuscitation Council UK. Focuses on importance of metrics in BLS: https://www.resus.org.uk/library/2021-resuscitation-guidelines/paediatric-basic-life-support-guidelines

European Resuscitation Council Guidelines 2021: Paediatric Life Support. Discusses use of metrics for quality improvement: https://www.cprguidelines.eu/

Myocardial ischaemia reperfusion injury and cardiopulmonary resuscitation quality improvement. Discusses CPR quality metrics: https://pubmed.ncbi.nlm.nih.gov/32620851/

Post-resuscitation care for infants and children: improving the chain of survival. Discusses post-resuscitation care metrics: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10788704/

2.8. Component 8: Functional and non-functional requirements

The paediatric life support system must incorporate both functional and non-functional requirements to ensure that it meets the needs of its users and effectively supports the intended business processes.

For functional requirements, the system must support secure user authentication and role-based authorization to ensure that only authorized healthcare professionals can access and modify the sensitive patient data. Additionally, it must allow for accurate entry, update, and retrieval of patient information, including demographics, medical history, and current health status. The system should support dynamic forms that adapt based on user input, display relevant fields, hide irrelevant fields to streamline data entry, and reduce the potential for errors. Real-time clinical decision support is crucial, guiding users through paediatric advanced life support (PALS) protocols based on the latest guidelines and the specific circumstances of each case.

The system should include automated calculations, such as drug dosages based on weight and timers for intervals such as rhythm checks and medication administration, to assist healthcare providers in delivering timely and accurate care. An alert and notification mechanism is also essential to remind users of critical actions and deadlines, such as the need for a rhythm check or administration of the next dose of medication. Integration with medical devices, such as defibrillators and monitors, should be supported to automatically capture and record data, thereby reducing the manual entry burden on healthcare providers. Additionally, the system must allow the export of collected data in various formats, such as CSV or PDF, for reporting and analysis purposes, which is crucial for monitoring performance metrics, conducting audits, and supporting continuous improvement initiatives. A detailed audit trail of all user interactions and data changes should be maintained to ensure accountability and support compliance with regulatory requirements. Comprehensive user training materials and support mechanisms, including user manuals, online help, and access to technical support, should be provided to ensure that users can effectively utilize the system.

Regarding non-functional requirements, the system must be capable of handling a high volume of data entry and retrieval operations efficiently, even during peak usage periods, and should be scalable to accommodate future growth in user numbers and data volume. High reliability and availability are critical, with minimal downtime, to ensure that the system is accessible whenever needed by healthcare providers, particularly during emergencies. The system must have an intuitive and user-friendly interface that supports efficient and error-free data entry, designed with the end user in mind, incorporating feedback from healthcare professionals to optimize usability.

Data security and privacy are paramount; the system must implement robust security measures to protect patient data from unauthorized access, breaches, and other security threats, complying with

relevant data protection regulations such as GDPR or HIPAA. It should be designed to interoperate with other healthcare systems and databases, enabling seamless data exchange and integration across different platforms and institutions. The system must be easy to maintain and update with a clear structure and documentation that allows for efficient troubleshooting, bug fixing, and enhancements. It should also be scalable to support an increasing number of users and data volume without performance degradation. Finally, the system should support multiple languages and be adaptable to different regional and cultural settings, ensuring that it can be effectively used in various geographic locations.

Further information

Functional Requirements:

Health Level Seven International (HL7) - Reference Information Model (RIM), Provides a framework for capturing and exchanging healthcare data: https://hl7.org/

Open-source Electronic Medical Record (EMR) Systems. Examples of systems with functionalities like secure access, data entry, and decision support: https://www.open-emr.org/

Institute of Electrical and Electronics Engineers (IEEE) - Software Engineering Standards. Provides guidance on developing software with functionalities like user authentication and data integrity: https://www.ieee.org/

Non-Functional Requirements:

National Institute of Standards and Technology (NIST) - Special Publication 800 Series, provides guidelines for securing information systems: https://csrc.nist.gov/publications

Health Information Portability and Accountability Act (HIPAA) Security Rule, US regulation for protecting patient data: https://www.hhs.gov/hipaa/index.html

General Data Protection Regulation (GDPR), EU regulation for data privacy: https://gdpr.eu/

Scalable and Maintainable Software Development Practices. Discusses approaches to building systems that handle growth and changes: https://www.martinfowler.com/articles/bottlenecks-of-scaleups/05-resilience-and-observability.html

Usability Engineering for Medical Devices, Focuses on user-centered design for medical systems: https://aami.org/

Interoperability Standards for Healthcare Information Systems, Discusses standards for seamless data exchange: http://hl7.org/implement/standards/index.cfm?ref=nav

3. Machine readable (L3)

ODK XLSForm is a structured template used to design forms for data collection using an Open Data Kit (ODK) or similar platforms. We tailored the form for paediatric life support and included various sections and data fields to capture essential information during the clinical decision-making processes. Here is an overview of the key components and structure of the XLSForm:

Sheets in the XLSForm

- Survey Sheet: The primary sheet where the questions and data entry fields are defined.
- Choices Sheet: This sheet contains predefined answer choices for multiple-choice questions in the survey sheet.
- Settings Sheet: This optional sheet can be used to set form metadata such as form title, version, and language settings.

The survey sheet is organized into several columns, each serving a specific purpose in defining the form.
type: Specifies the type of question or input field (e.g., text, integer, select_one, select_multiple, calculate, etc.).
name: The unique identifier for each question or field. This is used internally to reference the data collected.
label: The text that will be displayed to the user as the question or prompt.
hint: (Optional) Provides additional instructions or context for the user about how to answer the question.
constraint: (Optional) Defines a rule that the user's response must adhere to. For example, a numerical field might require that the value be within a certain range.
constraint_message: (Optional) The message displayed if the user's input violates the constraint.
required: Indicates whether the question is mandatory ('yes') or optional.
relevant: (Optional) Specifies conditions under which the question should be displayed, allowing for dynamic, context-sensitive forms.
default: (Optional) Sets a default value for the field.

The choices sheet includes options for questions that offer a predefined list of answers.
list_name: Links the choices to the corresponding question in the survey sheet.
name: The unique identifier for each choice option.
label: The text displayed to the user for each choice.

Key Sections and Fields

Identification Section

Patient Details: Captures the patient's unique identifier, first name, last name, date of birth, age, weight, address, and emergency contact information.

Initial Assessment

Cardiac Arrest Recognition: Determines if cardiac arrest has been recognized and the type of cardiac rhythm.

Advanced Life Support (ALS)

Interventions: Records details about ALS interventions such as defibrillation, drug administration, and CPR quality.

Settings Sheet

Form Title: Sets the title of the form.

Form ID: A unique identifier for the form versioning and tracking.

Dynamic Features

Relevance Conditions: Questions can appear or be hidden based on previous answers to streamline the data entry process and ensure only relevant information is collected.

Constraints and Validations: Ensures data quality by enforcing rules on user inputs.

Further Information

Open Data Kit (ODK) website: https://getodk.org/

XLSForm documentation: https://xlsform.org/en/

4. Executable (L4)

The deployment of the XLSForm for the paediatric life support system has been successfully accomplished utilizing the KoboToolbox platform, which is accessible at https://ee-eu.kobotoolbox.org. This deployment enables healthcare providers to access and employ the form in real-time, enabling data collection during paediatric life support interventions.

Deployed form: https://ee-eu.kobotoolbox.org/x/DpSC1aXV

With the use of KoboToolbox, the form is accessible from a range of devices, including tablets, smartphones, and computers, both in online and offline modes. This adaptability is especially valuable in emergency medical situations, where the availability of Internet connectivity may be inconsistent or non-existent.

The process of deployment entails uploading the XLSForm to the server of KoboToolbox, configuring the necessary settings for proper functionality, and testing the form to validate its performance. The platform's interface allows healthcare professionals to easily navigate and interact with the form, enabling them to quickly input and retrieve patient data. The KoboToolbox offers various features that enhance the paediatric life support system's functionality. These include automatic data synchronization, secure storage, and real-time data analysis capabilities. The platform ensures that all collected data are encrypted and securely stored, complying with data protection regulations such as GDPR. For deployments requiring HIPAA compliance, KoboToolbox offers options for users to run their own private instance on a HIPAA-compliant server. This protects patient information from unauthorized access and ensures confidentiality. Additionally, the integration of the KoboToolbox with medical devices enables the automatic capture and recording of vital signs and other critical parameters, reducing the manual data entry workload for healthcare providers. We chose this platform because it supports automated calculations and timers embedded in the XLSForm, which are crucial for guiding clinical decisions and ensuring timely intervention during paediatric life support.

Further information

KoboToolbox website: https://www.kobotoolbox.org/

KoboToolbox documentation: https://github.com/kobotoolbox/kobocat

Self-hosting for a private instance of KoboToolbox for HIPAA Compliance: https://community.kobotoolbox.org/t/requirements-to-install-kobotoolbox-on-a-self-hosted-server/20210

5. Testing, implementation, monitoring and evaluation strategy

5.1. Quality Assurance Testing: Risk-Based Testing Approach

The development of a risk-centered testing approach for the Clinical Decision Support System (CDSS) calls for the initial step of pinpointing and classifying potential risks. These risks are classified according to their influence on patient safety, system efficiency, data accuracy, and regulatory conformity. Essential categories encompass patient safety risks, such as flawed decision support logic, improper dosage computations, and delays in critical notifications; system performance risks, including system malfunctions, slow response times, and insufficiencies in performance during high-traffic periods; data integrity risks, comprising data loss, incorrect data synchronization, and security breaches in data; and regulatory compliance risks, encompassing non-compliance with healthcare regulations like GDPR, HIPAA, and others.

Once potential risks have been identified, it is crucial to prioritize them according to their severity and likelihood of occurrence. This can be achieved by utilizing a risk matrix, which assesses each risk on a scale of impact (categorized as critical, high, medium, or low) and likelihood (classified as frequent, occasional, or rare). It is essential to primarily concentrate on critical and high-impact risks when conducting testing efforts. To address the prioritized risks, specific test cases should be developed that target potential issues. Test cases should encompass both the functional and non-functional requirements of the Clinical Decision Support System (CDSS). Functional testing entails validating decision support logic, verifying dosage calculations, confirming the accuracy of alerts, and ensuring proper workflow execution. Performance testing involves conducting load testing to confirm the system's ability to handle peak usage, performing stress testing to identify potential system breakpoints, and verifying system response times under various conditions. Data integrity testing is focused on evaluating data synchronization between devices, examining data encryption methods, and executing data recovery tests. Compliance testing guarantees that data handling processes adhere to GDPR and HIPAA regulations, verifies audit trails, and checks user access controls.

In order to evaluate the effectiveness of the Clinical Decision Support System (CDSS) across various levels, it is necessary to conduct tests for L2, L3, and L4 translations. To assess the system's performance at the Operational Level (L2), scenario-based testing is employed. This testing method simulates real-world scenarios, such as a paediatric cardiac arrest in the emergency room, to verify that the CDSS provides accurate decision support and timely alerts. Additionally, end-to-end workflow testing ensures that the complete workflow, from initial patient contact to post-resuscitation care, functions correctly, with all system components interacting seamlessly. At the Machine Readable Level (L3), testing involves validating decision-support algorithms to ensure they are correctly implemented and cross-checking algorithm outputs against expected results. Data consistency checks are

conducted to ensure that data collected and processed by the CDSS remains consistent and accurate when translated into machine-readable formats. To evaluate the system's performance at the Executable Level (L4), deployment tests on the KoboToolbox platform are conducted. This ensures that the form is accessible, functional, and properly synchronized across devices. Furthermore, usability testing with healthcare providers is conducted to ensure that the system is intuitive and user-friendly, gathering feedback for necessary adjustments.

Automation and continuous testing are vital for ensuring the long-term quality of the system. Implementing automated tests for high-risk and repetitive areas, such as dosage calculations and decision support logic, enables early identification of issues. The use of Continuous Integration/Continuous Deployment (CI/CD) pipelines ensures that every code change is automatically tested before deployment, thereby significantly reducing the risk of defects in production. Real-time monitoring of the CDSS is implemented to promptly identify and resolve issues, using monitoring tools to track system performance, error rates, and user activity. Establishing feedback loops with healthcare providers allows for the continual collection of feedback on system performance and usability, enabling ongoing improvements and addressing any identified issues in a timely manner.

5.2. Implementation

The implementation plan for the CDSS is designed to ensure seamless integration and effective use by healthcare providers. The CDSS will be deployed via a cloud-based platform, which can be accessed through web browsers and mobile applications. This approach guarantees that healthcare providers can access the system from various devices, including tablets, smartphones, and desktop computers, both online and offline. To ensure seamless integration with existing systems, the CDSS will utilize standard APIs and HL7/FHIR protocols to ensure interoperability with Electronic Health Record (EHR) systems, facilitating smooth data exchange and reducing the need for duplicate data entry. Additionally, the system will interface with medical devices, such as defibrillators and monitors, to automatically capture and record vital signs and other critical parameters.

User training is a vital part of the implementation plan. Initial training sessions will be conducted for physicians, nurses, and paramedics, covering system navigation, data entry, decision support functionalities, and emergency protocols. To ensure continuous proficiency, ongoing education programs, webinars, and online tutorials will be made available. A dedicated helpdesk will be provided for technical support and troubleshooting. Regular simulation exercises will be conducted to ensure users are proficient in using the CDSS during real-life paediatric emergencies. Maintenance of the system will involve regular updates to incorporate the latest clinical guidelines and user feedback, deployed with minimal disruption to users. Robust security measures, including encryption, regular audits, and compliance with GDPR and HIPAA standards, will be put in place to protect patient data. System

performance will be continuously monitored to ensure high availability and quick response times, with any issues promptly addressed by the technical support team.

5.3. Monitoring and Evaluation

The monitoring and evaluation strategy will be executed in multiple stages. Initially, the focus will be on guaranteeing a seamless rollout and addressing any initial issues, with objectives such as the user adoption rate, initial user feedback, and system stability. As the system develops, the emphasis will shift towards optimization and enhancement based on comprehensive user feedback, targeting the efficiency of clinical workflows, minimizing manual errors, and improving clinical outcomes. In the long run, the overall impact on paediatric life support outcomes and the sustainability of the system will be evaluated, with objectives including long-term user satisfaction, continuous adherence to clinical guidelines, and integration with emerging medical technologies.

The influence of the CDSS can be considerable. On one hand, it can enhance clinical decision-making by providing immediate, evidence-based suggestions, leading to more precise and prompt clinical decisions. It is expected that the adherence to guidelines and standardized resuscitation processes will improve patient outcomes, resulting in higher survival and recovery rates. The system will streamline workflows by automating routine calculations and reminders, allowing healthcare providers to focus more on patient care while reducing their cognitive load. However, there are also potential drawbacks. Healthcare providers may struggle to adapt to the new system, which could temporarily affect efficiency. Furthermore, relying too heavily on the CDSS may diminish clinical judgment skills unless balanced with continuous education and training.

The evaluation methods will include data analytics to monitor key performance indicators, including the time to intervention, the accuracy of diagnosis, and patient outcomes. In addition, regular user feedback will be obtained via surveys and focus groups to pinpoint areas for enhancement. Clinical audits will be conducted to verify compliance with clinical guidelines and protocols. Outcome measurement will assess patient outcomes, such as survival rates, the incidence of complications, and long-term recovery, to gauge the CDSS's influence on patient care.

The CDSS is expected to have a positive impact in various ways, such as enhancing the consistency of care by ensuring standardized practices across providers, reducing variability, and improving the overall quality of care. It will also provide valuable support to clinicians, especially during high-stress situations, enabling them to make informed decisions quickly. The CDSS will facilitate ongoing improvements in paediatric life support protocols and practices through continuous data collection and analysis. However, there are challenges associated with the implementation of the CDSS, such as ensuring that all users are proficient with the new system, integrating it with various existing systems and devices, and maintaining healthcare providers' engagement over the long term. By developing a

robust plan for deployment, continuous monitoring, and regular evaluation, the Paediatric Life Support CDSS aims to significantly enhance the quality of care provided to critically ill children while supporting healthcare providers in delivering timely and effective interventions.