TITLE

The development of a clinical interface for a novel newborn resuscitation device; a Human Factors approach to understand cognitive user requirements.

Abstract

Background

A novel medical device has been developed to address an unmet need in standardising and facilitating heart rate recording during neonatal resuscitation. In a time critical emergency resuscitation, where failure can mean death of an infant, it is vital that clinicians are provided with information in a timely, precise and clear manner to capacitate appropriate decision making. This new technology provides a hands free, wireless heart rate monitoring solution that easily fits the clinical pathway and procedure for neonatal resuscutation.

To understand the requirements of the interface design for this new device, a human factors approach was implemented. This combined a traditional user-centred design approach with an Applied Cognititive Task Analysis (ACTA) to understand the tasks involved, the cognitive requirements and the potential for error during a neonatal resusciation scenario.

Method

Fourteen clinical staff were involved in producing the final design requirements. Two paediatric doctors supported the development of a visual representation of the activities associated with neonatal resucitation. This was used to develop a scenario based workshop. Two workshops were carried out in parallel and involved three paediatric doctors, three neonatal nurses, two advance neonatal practitioners and four midwives. Both groups came together at the end to reflect on the findings which emerged during the separate sessions.

Results

The outputs of this study have provided a comprehensive description of information requirements during neonatal resuscitation, and enabled product developers to understand the preferred requirements of the user interface design for the device. The study raised three key areas for the designers to consider, which had not previously been highlighted. These related to: 1) interface layout and information priority - heart rate should be central and occupy two thirds of the screen, device, 2) size and portability – to enable positioning local to baby's head and allow visibility from all angles and 3) auditory feedback - to support visual information on heart rate rhythm and reliability of the trace with an early alert for intervention, whilst avoiding parental distress.

Conclusion

This study demonstrates the application of human factors and the ACTA method, which identified user requirements previously not identified. This methodology provides a useful approach to aid development of the clinical interface for medical devices.

Keywords

Neonatal resuscitation; medical device; human factors; user centred design; applied cognitive task analysis

Introduction

Globally, each year there are approximately 3.6 million neonatal deaths (i.e. in the first 28 days of life) with 70% occurring on the first day of life,[1]. Up to 10% of newborns (79K/year in UK, 13M/year worldwide) require some form of resuscitation at birth, with an estimated 7 million babies worldwide requiring more advanced resuscitation,[2]. The correct, structured management of the resuscitation in the first few 'golden' minutes after birth is critical to prevent significant morbidity (e.g. cerebral palsy due to hypoxia) or death. There is strong evidence that standardised resuscitation training and algorithms significantly improve newborn outcomes and could reduce mortality by up to 30%,[2,3].

International newborn resuscitation guidelines highlight the importance of using the heart rate (HR) to guide resuscitation and stabilisation methods,[4]. However, many of the methods used to measure the heart rate are inaccurate or are technically challenging particulary in premature infants.

When assessing the HR, practitioners always have access to a stethoscope and use other technologies less frequently,[5]. HR assessment using the stethoscope, through auscultation, is inaccurate in about 1/3 of cases,[6,7] and is not continuous so needs to be done every 30 seconds so is time consuming, which causes a pause in resuscitation and can lead to errors.

This paper describes an enquiry invesitgating the design and use of a novel medical device, which has been developed to address the unmet need in standardising and facilitating neonatal resuscitation. In an emergency time critical resuscitation situation where failure can mean death of an infant it is vital that clinicians are provided information in a timely, precise and clear manner to support decision making. The nature of this context requires an interface which can ensure both the efficiency and reliability of staff to access the most critical information. A touchscreen interface was considered to be the best hardware solution. The work described here focuses on the development of the design requirements for a touchscreen interface, integral to this novel medical device.

To understand the requirements of this new device, and specifically the contributors to interface design, a human factors approach was implemented which combined a traditional user-centred design approach with an applied cogntitive task analysis (ACTA),[8]. The aim of which was to understand not only the tasks involved but also the cognitive requirements of clinicians. This study has enabled the generation of an interface specification. In addition the study's findings provide points of learning to other medical device developers and clinicians, looking to understand the complex requirements and information needs of clincians required during neonatal resuscitation.

Medical Devices to measure HR in neonates

Other common techniques for monitoring HR on the neonatal intensive care unit (NICU), such as electrocardiography (ECG) or pulse oximetry (PO), were not developed for resuscitation at birth. These systems are used less due to their reliability, delay in HR readings and practical issues e.g. difficulty ensuring adhesion to the skin,[5,9].

In the delivery room, ECG and PO sensors are connected to the main monitors by cables. This can make attachment more challenging and risks cold exposure with the potential for hypothermia; an independent risk factor for death in premature babies,[10]. Current resuscitation guidance for premature babies highlight the avoidance of hypothermia and so priority is given to drying of the baby's head, putting on a hat and placing the body (wet) in a plastic bag/wrap,[11].

To address the issues described a novel heart rate monitoring hardware solution using reflectance mode optical photoplethysmograpy, an optical sensor, has been designed. This has been integrated into a single use newborn hat, specifically for use on newborn babies requiring resuscitation. This solution aims to fit naturally into the existing care pathway allowing wireless, hands free, quick, continuous and accurate HR monitoring via a touchscreen interface, as well as minimising the risk of hypothermia. The effectiveness of the solution is a combination of two features. The forehead placement, where blood flow is preserved even in babies with a low HR (the forehead blood supply comes from the carotid arteries that supply the brain), and the sensor's patented optical arrangement and signal processing scheme, which has been proven to provide high signal quality from neonatal patients,[12]. Additionally, the hat uses wireless communication allowing greater flexibility in deployment than cable based solutions.

Human Factors/Ergonomics in medical device design

The value of Human Factors/Ergonomics (HFE) integration to medical device design and patient safety has become recognised over recent years,[13-17]; with formal recognition in standards,[18-21] and is a requirement of the European Medical Devices Directive 93/42 and its 2007 amendment for obtaining CE approval. Concerns still remain to the quality and effectiveness of the interpretation of all relevant standards and integration of HFE within the design/development process. There appears a lack of 'exemplar case studies' to illustrate how the design process and user-centred design can contribute to product design in healthcare, and how HFE should be routinely implemented, [22,23,24]. This is acknowledged with specific barriers identified within small and medium enterprises, such as University spin-out companies, [16].

This current study contributes to the body of evidence on the application of HFE methods to the formative evaluation of this novel medical device, as required by the relevant standards (21), through a collaboration between a University spin-out company, the School of Medicine and the Human Factors Research group within the University of Nottingham.

This current study has focused specifically on understanding human-computer interactions and user requirements for the computer interface of the device. The aims were:

1. To identify gaps in existing knowledge on user requirements for the interface design of a novel resuscitation device;
2. To represent the key design requirements to promote usability of the touchscreen interface of the device.

Method

This study collected and analysed data from intended and representative future users of the new device.

The ACTA method was selected for this study as it has previously been shown as beneficial to healthcare domains,[8,24]. The ACTA facilitates the elicitation of cognitive requirements from clinicians relative to a particular task and translates these for system designers into design requirements; for a full explanation of the method see,[8]. The ACTA has four key stages. Table 1 highlights how each stage of the method is relevant to understanding the task of neonatal resuscitation. For the purposes of this study the ACTA method was modified to accommodate clinical working practices and the simulation interview took the form of an interactive scenario based workshop.

Table 1 Description of The Applied Cognitive Task Analysis (ACTA)

1. Task Diagram	**2. Knowledge Audit Interview**
Method	
Interviews with 2 Subject Matter Experts (SME) familiar with the task of neonatal resuscitation **Interview 1** Task identification with SME 1: 150 minutes **Interview 2** Verification of task representation with SME 2, Identification of key/difficult cognitive tasks with SME 1 & 2: 75 minutes.	Interview with 2 SMEs - 180 minutes. Starting with the use of the knowledge audit probes (Supplementary file 1) to elicit general domain knowledge of how an expert may deal with a neonatal resuscitation, whilst exploring potential errors that novice users may make. Specific examples of how certain cues and strategies supported individual tasks were also explored.
Purpose	
To provide a broad view of the task and identify difficult cognitive components.	To highlight which aspects of the task require expertise and which cues and strategies are relied upon to understand the impact on the novice user.
Output	
a. Key tasks associated with neonatal resuscitation using sticky notes, Figure 1. b. Visual representation tasks using Microsoft Visio version 2013. c. Verification of task representation. d. Key/difficult cognitive tasks e.g. those requiring decision making, judgements, assessments or problem solving.	a. Identification of critical cues, interpretation of information to diagnose and predict situation. b. Identification of strategies relied on by expert users. c. Identification of potential for errors in novice users.

3. Simulation Interview - Workshop	**4. Cognitive Demands Table**
Method	
Observation of a challenging scenario (Textbox 1) involving the task of neonatal resuscitation. Each key task is queried to explore the critical cues, assessment, actions and potential for error: 1. What actions, if any, would you take at this point? 2. What do you think is going on here? What is your assessment of the situation at this point in time?	To summarise and integrate the information obtained from the previous 3 steps and interview data gathered prior to the study.

3. What pieces of information led you to this situation assessment and these actions? 4. What errors would an inexperienced person be likely to make in this situation?	
Purpose	
To determine the cognitive process involved with key tasks and potential error.	A comprehensive record to focus the findings to the required project goals.
Output	
a. Identification of difficult cognitive components of task, information and priorities. b. Identification of critical cues relevant to decision making for each key task and potential for errors in novice users. c. Essential and desirable information requirements. d. Group mock-up of interface design, on a cardboard model. e. Individual annotation of a paper-based image of the intended interface screen.	a. A spreadsheet of the data collated through the study

The workshop aimed to recruit a range of healthcare professionals, with varying levels of experience and representative of those who might have involvement in neonatal resuscitation procedures. A convenience sampling approach was adopted for the recruitment of participants, from two large tertiary based teaching hospital in the United Kingdom. Posters and flyers advertised the details of the study and 12 staff with experience of neonatal resuscitation, were successfully recruited Table 2.

Table 2 Details of workshop participants

Job role	Years/ range of experience	Participants (No.)
Neonatal trainee Nurse	2	1
Neonatal Nurse	1-16	2
Midwife	0-25	4
Paediatric/Neonatal Doctor	1.5 - 5	2
Neonatal clinical Nurse educator	30	1
Advanced Neonatal Nurse Practitioner	15 - 22	2

To explore the cognitive requirements further and elicit insight from all practitioners, the workshop protocol divided the practitioners into two groups of 6, split evenly to ensure equal numbers of each job role for each group; with the exception of the clinical educator and trainee who went in different groups. This allowed different levels of experience and job roles to explore the same simulation, Box 1. Ethical approval was given by the University of Nottingham and all participants gave their informed consent.

The two researchers (LP & AL) familiarised themselves with the task of neonatal resuscitation through observing videos of a simulated resuscitation provided by the two Subject Matter Experts (SMEs) (LS & CH, neonatal doctors with 8 years resuscitation experience) and through follow up interviews to clarify points of uncertainty and task identification. This was necessary for practical reasons as the observation of such events cannot be planned. A review of the national neonatal resuscitation algorithm,[11], provided the researchers with an understanding of current UK practice. Finally, relevant international and British standards,[18-21] were consulted to provide direction for the designers on medical device recommendations.

Past Clinical History

A first time mum at 42 weeks gestation presents with baby stuck and due to shoulder dystocia.

She has a slight fever and no past medical history but has received diamorphine during her labour. Labour was induced through artificial rupture of the membrane. She has prolonged rupture of membranes and labour has been ongoing for 24 hours.

The baby's head was delivered 10 minutes before baby's body and airway appears clear.

1. Assessment observations

Baby presents floppy, white and not responding to vigorous stimulus. HR <60 with stethoscope and no respiratory effort evident.

2. Progression of intervention

After 2 sets of 5 inflation breaths still no chest movement.

3. Chest compressions commenced

The chest moved but HR remained slow.

Textbox1 Simulation of a challenging scenario used to probe practitioners during workshop

There were five outputs produced from this study, these were achieved through the outputs listed in Table 1:

1. A high level representation of the tasks required to identify the need and completion of neonatal resuscitation	Table 1, Task Diagram: a-c;
2. Identification of the key/difficult cognitive requirements for neonatal resuscitation tasks, critical information and decision points	Table 1, Task Diagram: d and Knowledge Audit Interview: a-c;
3. Analysis of the cognitive demand associated with key tasks and potential errors	Table 1, Knowledge Audit: a-c and Simulation Interview: a-b;
4. User opinion on interface design options to support cognitive requirements, reduce potential for error and record	Table 1, Simulation Interview: c-e;

neonatal resuscitation events	
5. A comprehensive outline of user and design requirements for the interface design and relevant standards	Table 1, Simulation Interview: c-e and Cognitive Demands Table: a

Findings

The practitioner workshop involved paediatric doctors (3), neonatal nurses (3), advanced neonatal nurse practitioners (2), Midwives (4) with between 0 – 30 years' experience, and an average of 11 years. The workshop and SME interviews identified factors relevant to both device and interface design not previously considered by the design team.

Context of neonatal resuscitation tasks

The critical characteristics of a neonatal resuscitation were described by practitioners as time pressured and unpredictable; albeit well-rehearsed. This is likely to be an emotional and stressful situation for the parents involved. The location of a neonatal resuscitation may vary and could include: labour suite, midwife led unit, birthing pool room, operating theatre, patient's home or an ambulance. Participants suggested that the portability of the system should therefore be prioritised. Practitioners considered the attachment features of the device could replicate those of a car satellite navigation screen, with options to secure (which implies the device is attached but can be adjusted) and rotate the screen to ensure a continual good line of sight. The physical environment suggests lighting may also vary e.g. bright theatre lights, variability in lighting within a single resuscitation. The device may also remain in use when transferring the baby between delivery and the neonatal unit or in ambulances, hence resistant to vibration and movement.

Alarms were considered as useful only in certain contexts and the type e.g. frequency, pitch of alarm required sensitivity in design to avoid undesirable consequences for parents and clinicians,[25,26].

The device may be used in the context of other medical devices e.g. Resuscitaire (portable 'platform' for neonatal resuscitation integrated with required equipment). Compatibility between equipment is essential to ensure usability and reliability.

Tasks relevant to neonatal resuscitation

The SME interviews (interviews 1 and 2 Table 1) suggested seven relevant high level cognitive tasks and produced the first study output, a high level representation of the tasks required during neonatal resuscitation (see Supplementary file 2- worksheet ‘relevant cognitive tasks’):

1. Establish history of events
2. Assess baby
3. Interpret HR
4. Interpret respiration
5. Support respiration
6. Continual re-assessment
7. Decide to act

These tasks were considered based on the core principles of the task analysis [27]. The top layer represents ‘what’ has to be done (Supplementary file 2 Tasks 1.0 – 7.0) and further descriptions in the layer below describing ‘how’ it has to be done (Supplementary file 2 Sub Tasks 1.1 – 7.6). A visual representation was shared with clinicians within the workshops and a consensus reached for the final presentation. Figure 1 illustrates a sample of the representation shared.

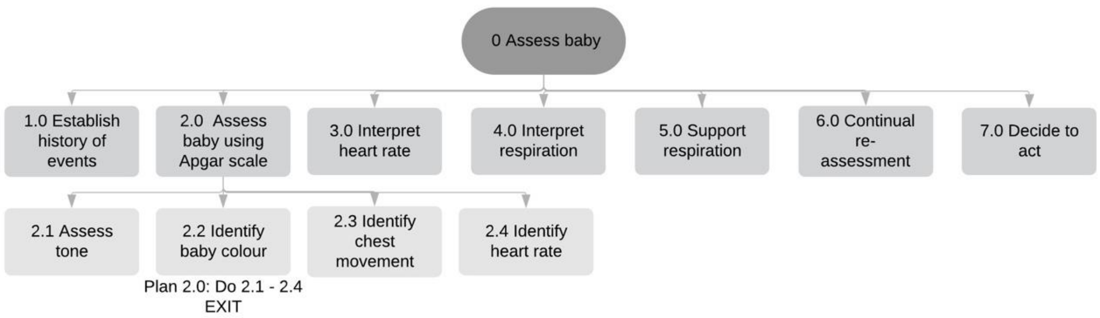


Figure 1 A sample of the representation of the task analysis completed with clinicians to illustrate neonatal resuscitation

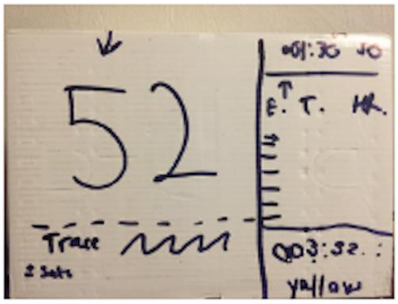
Nine tasks in total were agreed upon, by the SMEs and workshop participants, to have a cognitive element to them. Supplementary file 2 highlights these nine tasks in blue within the worksheet ‘relevant cognitive tasks’. The nine tasks included: receive antenatal history, assess baby using Apgar score,[28], interpret chest movement, interpret heart rate, decide on action, direct view and clearing of airway, assist breathing, decide to intubate and decide to medicate.

Cognitive requirements, demands and potential error

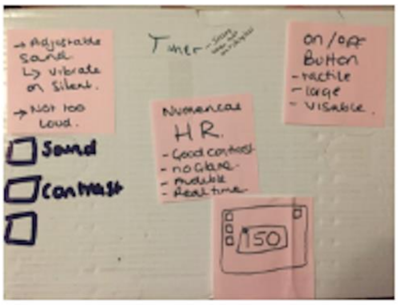
The interviews completed during the development of the task diagram and the knowledge audit interview elicited information relevant to the difficulty and nature of the cognitive work including: cues, assessment, judgements, problem solving, decisions, and actions combined with potential challenges and errors and strategies relevant to the nine cognitive tasks.

The findings from these first two stages of the ACTA method were verified and enriched by data obtained during the Simulation Interview workshop. The data from all three stages of the ACTA method were collated within a spreadsheet (a template of the one used is provided with a sample of data in supplementary file 2) and then combined and simplified to produce a cognitive demand table for each of the nine cognitive tasks, see Table 3. For an example These created the second and third study outputs.

The two workshop groups further informed the fourth and final study outputs, which produced a specification and illustrated mock ups with notable differences in the priorities for design. One group preferred to protect the simplicity of the device and represent heart rate as the only physiological marker, with an event timeline running in the background. The other group preferred to include oxygen saturation and a visible record of an event timeline, Figure 2.



Practitioner group A mock-up



Practitioner group B mock-up

Workshop Design Interface mock up A
(numbers are arbitrary)

Workshop Design Interface mock up B
(numbers are arbitrary)

Figure 2 Mock-up of interface designs produced during simulation interview

After the two workshop groups had worked through the simulation independently the groups came together and presented their specifications and mock ups. Individual participants were then asked to reflect on the work they had done in their groups and also the presentation from the other groups to produce their own personal interface design. These individual contributions were analysed to interpret the groups preferences and produce cumulative representations of the data as a Heat Map, Figure 3. This indicates consensus on the location of interface information sources summarising individual location preferences (12 practitioners) of the 5 information types. The x axis indicates the width of the screen and the y axis indicates the height of the screen. Each screen was broken up into 24 areas (6 along x axis and 4 along y axis). The colour bars are normalised against the maximum number of practitioner votes for each area on the Heat Map.

Table 3 Cognitive demand table for 'assess baby using Apgar score'

Difficult cognitive element	
Assessment of baby based on Apgar scale to inform decision and actions	
Why difficult	• Interpretation of Heart Rate (HR) and chest movement relative to normal parameters. • Judgement of accuracy and reliability of HR display. • Relies on previous experience and recognition of 'normal' HR and chest movement to inform decision and actions. • Multiple tasks in short time frame - visual check of HR, chest movement, tone and skin colour. Continual re-evaluation every 30 seconds. • Requires expertise to ensure decision making within short timeframe and potentially stressful environment.
Common errors	• Accuracy in interpretation of HR. • Fail to recall normal HR and chest movement. • Estimation/recall of time elapsed between key events. • Fail to recognise when to act e.g. call for help, intubation. • Avoidance behaviour - fear to act/'failure to rescue'. • Over reliance on technology (lacking reliability) and colleague's earlier assessment. • Quiet breathing missed e.g. Preterm babies. • Lighting can distort baby colour
Cues and strategies	**Cues** • Absent HR, HR <60 beats /min • HR >100 • Floppy • White colouring • No breathing/gasping • Stressful environment • Absence of baby crying **Strategies** • Consider how to obtain support with minimal alarm to parent? • Continually question interpretation/reliability of information. • Continual re-assessment 30 seconds and after 1,5,10 minutes. • Closer inspection e.g. ear to mouth, observe rib cage and abdomen, listen for absence of sound or gasping.

In summary the stages within the ACTA method provided:

Task diagram

- A breakdown of the physical and cognitive activities involved in the context of neo natal resuscitation;
- Visual representation of SME perspective of the key cognitive activities;

Knowledge audit interviews

- Detailed descriptions of the nature of the cognitive work required, cues and strategies relied upon and potential for error;
- Insight into differences between expert and novice practitioners in the context of neonatal resuscitation;
- Examples of previous experiences, which revealed influences of the people involved/present, environmental factors and the emotional nature of the context;

Simulation interview (workshop)

- Verification of the task diagram and understanding of cognitive requirements; based on a broader group of experts;
- Additional insights into cognitive work required, cues and strategies relied upon and potential for error; based on the experience of the participants ;
- Consideration to future users and healthcare contexts;
- Design suggestions which reflect practitioner's preferences and understanding of the cognitive activities and potential errors discussed;

Cognitive demands table

- An assimilation of all of the above findings in a usable format to inform and justify the development of the design requirements.

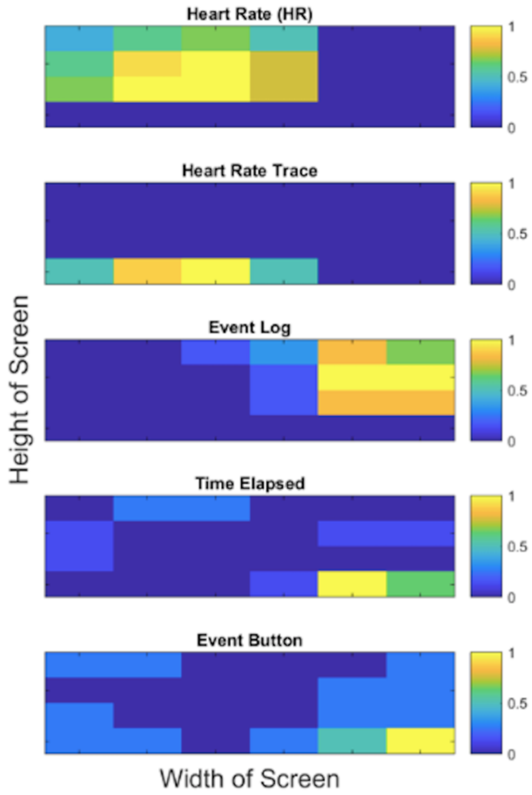


Figure 3 Heat Map which indicates consensus for the location of key information sources

Themes relative to essential and desirable characteristics for the interface were elicited. These were combined with recommendations from international standards to produce a set of design requirements, [18,21,29-33]. A typical example of the information contained within these requirements are provided in Textbox 2. The final decision for timer position was influenced by users and optimisation of the display screen space. The information obtained informed the final design developed and indicated priorities for future usability testing. This information and the heat map was developed as a block diagram and informed the Graphical User Interface concept, illustrated by Figure 4.

Textbox 2 Design requirements relating to information layout

Information Layout

Essential characteristics - HR should be central and the largest text on the screen. This should allow visibility from all angles and the HR information should occupy two thirds of the screen.

Desirable characteristics - Divide screen to have a margin on the side of screen with buttons to mark events. One group suggested a visible timeline to be illustrated. The second group did not agree with any more information than essentially required e.g. HR.

International standards and recommendations - hierarchy to the content of information displayed should be implied by the layout. The most important information should occupy priority space, typically top left for large screens and central for smaller screens, with adequate blank space and borders to separate information sources

Discussion

To the authors knowledge the ACTA method has not been used in the development of resuscitation devices.

There are many HFE methods relevant to the design process [34, 35]. The value of methods suitable for identifying user requirements was considered by [15] and suggests focus groups and user testing as both beneficial. The application of cognitive task analysis (CTA) in medical device design does not appear to be well applied [16] despite recognition that this could provide a useful tool to the domain of healthcare [8]. The application of such methods rather than just the completion of the traditional hierarchical task analysis, are well recognised for their benefit of formatively understanding critical cues, decision making, judgements, constraints and potential errors in the context of a work situation, however, they are also considered resource intensive [8, 36, 34].

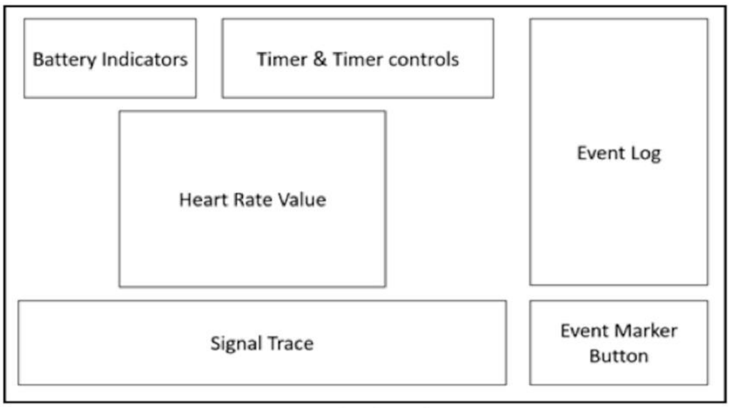
The ACTA was developed to address some of these issues. The method is intended to allow practitioners within the area of work studied and system designers to elicit cognitive requirements relative to task performance and translate these into design requirements [8].

This approach was considered desirable for the current study. Firstly, as a method to understand user decision making and critical information requirements from the intended interface. Secondly, to illustrate a method that could be applied by practitioners themselves in future design/evaluation of medical devices. Thirdly, pragmatically the time available suggested efficiency was desirable in any method selected; which the ACTA offered.

The method has allowed the tasks required for neonatal resuscitation to be fully considered in relation to cognitive requirements, actions and potential errors. This participatory approach has offered a systematic analysis of the resuscitation process, described as 'logical and rigorous' by the SMEs. Successful implementation within the context of healthcare has been suggested as benefiting from such participation to ensure relevant stakeholders influence the design of an intervention to fit their own contexts,[37]. ACTA allowed user requirements to be identified specific to different contexts and stages within the resuscitation process.

The success of the ACTA approach came from engaging participants from different job roles to consider contexts familiar to them and ensured practitioners considered which cues have greatest significance to completing the required tasks, likely errors and how interface design

can support these tasks. The outputs of this study have provided a comprehensive description of information requirements during neonatal resuscitation, and enabled product developers to understand the core and preferred requirements of the user interface design for the device. These outputs have been used to develop an interface which prioritises simplicity and provides a set of user requirements, to test the device against during future testing, Figure 5.



a) Block Diagram

b) Graphical User Interface

Figure 4 Block diagram (a) and the Graphical User Interface concept (b) developed to locate the main information sources on the screen.

Figure 5 Resuscitation device comprises of a single-use thermally insulating Hat which communicates wirelessly (via battery powered Modules) with a Display mounted on the resuscitation table.

The study raised three key areas for the designers to consider, which had not previously been identified. These included:

- Interface layout and information priority
- Size and portability of device
- Auditory feedback.

The amount of information, which ultimately influences the size of the screen, will be determined by the intended function of the technology. Considering the task of neonatal resuscitation it becomes apparent that, early on in the process of resuscitation, HR is the key indicator used by practitioners. This information was prioritised by both groups and all individual designs of the interface. Some preferred that this alone should be the function of the device. It was considered desirable to ensure the device had a relatively small interface which could be positioned freely and local to the baby's head. The auditory feedback proposed by practitioners was to support visual information and interventions early on in the resuscitation process. The nature of the feedback should communicate information on HR - rhythm and reliability of the trace. The practitioners went further to suggest that with different auditory settings the device could be used as a monitoring device within a neonatal unit, not previously considered by the developers. The implications of auditory feedback raised the importance of considering both practitioners and patient representatives e.g. parents within future usability testing,[37].

An integral timer was also considered essential as would serve as an indicator for the timeline of events within a resuscitation. Currently the clock started at the time of birth is integral to the Resuscitaire, future user testing needs to explore how the novel device will influence this practice.

Consideration to the community setting suggested there may be less access to oxygen saturation devices. The novel HR device was suggested as offering the potential to compensate for this absence. Within secondary care the oxygen saturation devices were considered as useful when intubating to secure an airway for the transfer to a neonatal unit. Including oxygen saturations implied greater usability for the device in alternative situations and work contexts in the future.

However, practitioners also acknowledged a risk where oxygen saturations could actually be a distraction, for less experienced practitioners, from the critical cue of heart rate which is considered a better indicator of neo natal status and relied upon by the expert practitioner.

The benefit of having a HR reading immediate to the baby's head, on the wireless Module, was considered of high value. This would reduce the need to continually look between the baby's head and an interface screen, where the HR would be viewed at a distance. Suggestions were made relating to the functionality of the wireless Module, Figure 1.; including how it could be the component within the device used to download contextual information such as an event log. This would avoid the need for a separate USB memory stick or disc to store data, reducing the risk of lost device components or information, a current problem with other medical devices.

Failure to recognise or acknowledge a deteriorating HR was considered. The device design could incorporate feedback to increase awareness of this critical cue. A change in screen colour was suggested as the preferred prompt by some, however, further usability testing is required to find out if this improves practitioner performance in reacting to a deteriorating HR or is perceived distracting or even anxiety provoking. How colour is used on the interface will also need to be explored, using colour convention guidance and usability testing,[18,21,30,31].

The final decisions made on interface layout were based on the optimisation of the screen by the design team. 'Future proofing' the device was also considered during the workshop and generated an enthusiastic discussion on how an additional, but linked, mobile device could be used to assist a designated scribe in recording key events within the resuscitation timeline. Currently the accuracy of a written report of neonatal resuscitation is variable, usually involving the most inexperienced team member to scribe. Future electronic records were proposed as complementary to an event marker control, operated by those delivering or supporting the resuscitation, whilst recognising that the timing may be slightly delayed. However, this was considered sufficient to develop a retrospective view of the sequence of events. The electronic recording of these data were considered of significant value for those in governance roles, clinical learning and audit.

Strengths and Limitations

The ACTA method provides an efficient, comprehensive and participatory approach capable of understanding user decision making and critical information requirements from the intended interface. Practitioners discussed the potential for this device beyond the original context considered by the developers.

The limitations of the study were in the sampling of clinicians. Volunteers led to the larger ratio of nurses and midwives to doctors. However, the SMEs were experienced doctors in neonatal resuscitation and fully engaged with the whole study. Limitations on this study have constrained further development of the interface and device, simulation and usability testing should ensure the views and suggestions raised by participants can be tested and translated into a real-world device.

Conclusion

This is the first study to have applied the ACTA approach to elicit user requirements for a novel device for neonatal resuscitation. This study demonstrates the application of human factors to inform the development of resuscitation devices, and more generally for medical device developers and clinicians in the design and evaluation of medical technologies.

The study has provided user requirements previously not identified and details about the variables which should inform future usability testing of the interface developed.

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Conflicts of Interest

Dr Carpenter reports on other work by SurePulse Medical Limited, outside the submitted work, he is the CEO of this company. Professor Barrie Hayes-Gill and Dr. Sharkey are unpaid non-executive directors of SurePulse Medical Limited all are shareholders. SurePulse Medical Limited are the developers of University of Nottingham research into vital sign monitoring technologies for newborns. The company Surepulse Medical Limited have a filed International Patent WO 2017/149325.

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Figures

Figure 1 A sample of the representation of the task analysis completed with clinicians to illustrate neonatal resuscitation

Figure 2 Mock-up of interface designs produced during simulation interview

Figure 3 Heat Map which indicates consensus for the location of key information sources

Figure 4 Block diagram and the Graphical User Interface concept developed from the block diagram.

Figure 5 Resuscitation device comprises of a single-use thermally insulating Hat which communicates wirelessly (via battery powered Modules) with a Display mounted on the resuscitation table.