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THE ROLE OF SIMULATION IN NEONATAL AND PEDIATRIC TRAINING AND RESEARCH

Doctoral Thesis

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ABSTRACT

Introduction

From a pediatric perspective, the two main types of simulation-based research are: studies that assess the efficacy of simulation as a training methodology and studies where simulation is used as an investigative methodology.

Aim of the study

Overall, the aim of the research activity is to inquire the use of simulation as investigative methodology in pediatric and neonatal settings.

Study design

Previously, we investigated the current use of simulation in pediatric fellowships in Italy in order to understand the state of the art and the expectations of pediatric residents with regard to simulation-based training and research. Furthermore, we developed suitable simulated scenarios for pediatric training and research.

As second step, we evaluated technical (TS) and non-technical (NTS) skills in a sample of Italian pediatric residents using a neonatal resuscitation scenario;

Finally, we aimed to evaluate the accuracy of NeoTapAS in reliably determining HR from auscultation in a high-fidelity simulated newborn resuscitation scenario.

Results and future perspectives

Firstly, we highlighted that an extremely high percentage of pediatric italian residents spent less than 5 hours/year in simulation-based education. Secondly, the mean compliance to last ILCOR recommendations about neonatal resuscitation was 59 % and a very low compliance (< 30%) was observed for a number of important technical items. Finally, NeoTapAS showed a good accuracy in estimating HR and it could be an important resource for neonatologists in delivery room resuscitation

As future perspective, we designed a new simulation-based multi-center research ("*Simarrest*") in collaboration with University of Padua in order to identify gaps about in-hospital pediatric cardiac arrest management in a standardized setting.

RIASSUNTO

Introduzione

Da un punto di vista pediatrico, i due principali tipi di ricerca basata sulla simulazione sono: studi che valutano l'efficacia della simulazione come metodologia e studi in cui la simulazione viene utilizzata come metodologia investigativa.

Scopo dello studio

Lo scopo generale della presente attività di ricerca è quello di indagare l'uso della simulazione come metodologia investigativa in contesti pediatrici e neonatali.

Disegno dello studio

Da principio, è stato indagato l'uso della simulazione nelle scuole di specializzazione pediatriche italiane al fine di comprendere lo stato dell'arte e le aspettative dei medici in formazione riguardo al training e alla ricerca basate sulla simulazione. Inoltre, abbiamo sviluppato adeguato scenari clinici simulati per la formazione e la ricerca pediatrica.

In secondo luogo, sono state valutate le competenze tecniche (TS) e non tecniche (NTS) in un campione di medici in formazione utilizzando uno scenario simulato di rianimazione neonatale.

Infine, è stata valutata l'accuratezza di una nuova tecnologia (*NeoTapAS*) nel determinare la frequenza cardiaca in uno scenario simulato di rianimazione neonatale.

Risultati e prospettive future

In primo luogo, è stato osservato che un'alta percentuale di specializzandi italiani in pediatria ha speso meno di 5 ore/anno in attività basate sulla simulazione. In secondo luogo, la conformità media alle raccomandazioni ILCOR sulla rianimazione neonatale è stata del 59% ed è stata osservata una *compliance* molto bassa (<30%) per importanti skills tecniche. Infine, in un setting simulato, NeoTapAS ha mostrato una buona precisione nella stima della frequenza cardiaca e potrebbe rappresentare una risorsa importante nella gestione della rianimazione in sala parto.

In prospettiva, è stato avviato un nuovo progetto di ricerca (*Simarrest*) in collaborazione con l'Università di Padova, al fine di identificare *gaps* nella gestione degli arresti cardiaci intra-ospedaleri in un setting standardizzato.

INTRODUCTION

Health care simulation can be defined as a tool, device and/or environment with which the learner or subject interacts to mimic an aspect of clinical care[20]. The technologies used to enable health care simulation include a wide variety of products and devices, including mannequins (with varying degrees of realism), computer/screen-based simulators, inert animal products, task trainers, and human cadavers.[12,17,33,61,62] This technology, when applied for training health care providers, is created or adapted to help address practical clinical problems. The field of pediatric simulation has grown rapidly in the past decade, both as an educational intervention and as an investigative methodology.[1,2,3,6,7, 10,11,31,32]

Research using simulation as an investigative methodology leverages the standardization provided by simulation to answer diverse research questions that otherwise could not be answered feasibly, safely, ethically, or in a timely fashion in clinical settings. The simulated environment is used as an experimental model to study factors affecting human and systems performance in health care. Mannequin-based simulation has been particularly useful in this context.

Many aspects of neonatal-perinatal medicine are characterized by decisions that carry life-or-death outcomes, procedures that must be successfully completed under intense time pressure, and highly charged emotional situations that challenge both family members and health care professionals alike. A number of studies involving comparisons of various procedures during resuscitation and design of devices such as code carts have been published in recent years, illustrating the utility of conducting research in simulated, rather than real environments.[4,5,28,29,30, 55,

SIMULATION BASED LEARNING

Approximately 4 million babies are born in the United States every year; of these, around 10% require some degree of resuscitation, with 1% needing extensive resuscitative efforts such as chest compressions, intubation, and delivery of medication.[34,65] Many different types of health care professionals are responsible for caring for newborns at the time of birth and in the days and weeks that follow.[8,9] These professionals include, but are not limited to, neonatologists, pediatricians, family practitioners, obstetricians, midwives, neonatal nurse practitioners, nurses, and trainees at

all levels in these disciplines. Given the large number of births, the frequency of resuscitation, and the diversity of professionals bearing responsibility for caring for patients in the neonatal period (the first 28 days of life), the need for effective means of acquisition and maintenance of the skill sets necessary to deliver safe and competent care is of tremendous importance. Traditionally the apprenticeship model of assuming graduated responsibility for the care of real patients has been used to address this need. Unfortunately, the assumption underlying this model—that placing a trainee in a supervised clinical environment for a set period of time will allow him or her to experience a sufficient number and breadth of clinical cases to ensure the ability to practice independently and safely in the community does not always prove to be true.[8,9] Similarly, maintenance of skill cannot be guaranteed by the routine, non-mentored delivery of patient care. Therefore, a new paradigm of skill acquisition and maintenance is required.[27,49,53,58,59]

Whereas teaching is something that is (passively) done to trainees, learning is something that trainees must (actively) do themselves. Because not everything that is *taught* is necessarily *learned*, programs that best facilitate skill acquisition in trainees are those that focus on learning, rather than on teaching.[12,16,19] Traditional didactic programs are passive by nature, and the settings in which they are held are typically isolated from realistic cues, distractors, and time pressure; thus, such programs are unable to prepare learners adequately for all of the challenges inherent when working in the real environment. Although learning in a real environment during the actual delivery of patient care may appear ideal at first glance, a deeper analysis reveals otherwise. The most obvious problem with using the real environment as the primary source of skill acquisition and maintenance is that any mistake could prove lethal to patients. The pace of actual clinical care conducted in the real environment with real patients is often too fast to allow trainees to take full advantage of the learning opportunities therein. Moreover, typically there is no way to ensure that all important learning opportunities will present themselves in the real environment during the time that the trainee is present. Finally, the real environment is also a very expensive environment and is populated with a number of professionals whose job description may not include providing learning opportunities for trainees.[14,15,18] Learning is best facilitated when the learning opportunities are

tailored to meet the needs of the learners. Training models that offer the same content in the same fashion to all learners (thus implying that competency can be attained and maintained simply by spending a particular, often arbitrary, amount of time at a task) fail to recognize that adults have different strengths, weaknesses, and life experiences and acquire and maintain different skills at different rates.[35] Some characteristics of effective adult learning strategies include the following:

- Focus on active rather than passive learning activities
- Integrate skill sets while performing under realistic conditions
- Emphasize competency (the ability to perform successfully) rather than compliance (adherence to rules, such as participation in an activity for a predetermined period of time).

It is much easier to design and implement exercises that are teacher-centric and targeted at the needs of the average learner rather than to develop programs that tailor the learning to meet the needs of individual learners; therefore, there are few interventions that are truly effective at uniformly facilitating the acquisition of necessary skills in diverse groups of learners.[23,24,35]

Any discussion of learning in health care must start with what it is that can be learned.[42] There are three "skill sets" that may be acquired and refined by health care professionals:

- What we know in our brains **(cognitive skills or content knowledge)**
- What we do with our hands **(technical skills)**
- How we employ the first two skill sets while caring for patients and working under realistic time pressure with our colleagues **(behavioral skills)**

Content knowledge is the skill set most familiar to learners and is typically the major (or only) skill set that is formally evaluated, usually through written or online tests. Technical skills such as intubation are critical to neonatal care. Despite their importance, such skills are most commonly practiced at skills stations using models that poorly represent neonatal anatomy and physiology and are evaluated by a subjective assessment of performance that is isolated from the time pressure intrinsic to the real environment.[39,40] Behavioral skills (including but not limited to leadership, teamwork, and effective communication) are critically important to successful patient

outcomes (Table 1). Unfortunately, these important skills are rarely, if ever, specifically addressed in learning programs directed at health care professionals.[51,52] Many patient care tasks actually incorporate elements of all three of these skill sets. Intubation of the newborn is one such example. Far from being simply a technical skill, effective and safe intubation requires coordination and integration of multiple cognitive skills (knowing the indications for intubation and the signs of successful and unsuccessful intubations), sequential discrete technical skills (assembling, testing, and inserting the laryngoscope), and a number of behavioral skills (effectively communicating observations and needs, evenly distributing the workload, and delegating responsibilities), all of which must also be accomplished in a time-efficient manner.

Table 1

Strategic Behavioral Skill
Know your environment.
Anticipate and plan
Assume the leadership role.
Communicate effectively.
Delegate workload optimally.
Allocate attention wisely.
Use all available information.
Use all available resources.
Call for help when needed.
Maintain professionalism.

Simulated clinical scenarios coupled with debriefings (in which discussion of what went well and what could be improved upon) provide rich learning experiences that equal or exceed those of other learning methodologies.[25,57] Although undoubtedly some learning takes place during active participation in scenarios, trainees perceive that most of the learning occurs during the debriefing

when time is allotted for self or facilitated reflection on performance.[50] This perception is supported by years of anecdotal experience using simulation in high-risk domains as well as decades of research in the science of adult learning.

Much has been made of the importance of the concept of fidelity in simulation-based learning. Simulation fidelity is typically thought of in terms of its physical, biologic, and psychologic elements. Physical fidelity refers to the realism of the physical space in which training occurs; this space is made to look real by including appropriate working medical equipment, fluids, pharmacologic agents, beds, and the other elements necessary for patient care. Biologic fidelity includes the patient simulators and standardized patients as well as the human beings acting as confederates during the simulation, playing roles designed to assist the evolution of the scenario.[24,56] Patient simulators have been described as high, medium, and low fidelity; unfortunately, there is no standardized definition of simulator fidelity in health care. In reality, no physical patient simulator currently in use bears close resemblance to a human being, either in terms of anatomy or physiology. The use of the term high fidelity when describing the current generation of patient simulators more likely refers to high complexity or high cost rather than any intrinsic similarity to a living human being. Finally, all of the previously mentioned elements interact with the mindset brought into the scenario by the learners to create a sense of realism or psychologic fidelity. The overall goal of simulation-based learning is to provide learning experiences that closely mimic the conditions encountered when working in the real environment. The major difference between the simulated environment and the real environment is the absence of real human patients.[47] Although debate continues in the health care simulation community as to how much fidelity is necessary and although some may argue that the higher the fidelity of the scenario to real life, the better the learning opportunity, it should be understood that as long as sufficient attention is paid to providing the key (not all) visual, auditory, and tactile cues for learners, allowing them to form a shared mental model of the nature of the situation that they are facing, they will have the opportunity to work effectively to resolve the clinical problems that become manifest during the scenario and therefore achieve the learning objectives.[21,41]

Simulation-based learning provides many obvious advantages over more traditional training methodologies. Because patient simulators replace human beings, there is no risk to patients; invasive procedures can be practiced without the fear of patient harm or medical liability.[36,44] Unlike what happens in the real environment, learning opportunities using simulation can be scheduled at convenient times and structured so that specific learning objectives are consistently achieved. Simulation-based learning is an ideal methodology for allowing learners to practice integration of multiple skill sets while working under highly realistic and often stressful conditions. Rather than being directed solely at the individual, simulation easily accommodates the learning needs of multidisciplinary teams. Simulation-based learning activities can easily be scaled in intensity to meet the needs of learners at all levels of experience, and they can be used to foster both the acquisition and maintenance of particular skills.[36,43,54,64] It can also be hypothesized that learners who participate in simulation-based exercises likely will be better prepared and will need less supervision when entering or re-entering the real environment (Table 2).

Table 2.

Advantages of Simulation
Presents no risk to human patients
Permits training in environments usually inaccessible to less experienced trainees
Can be tailored easily to the needs of individual trainees regardless of level of experience
Allows practice without interruption or interference
Fosters integration of cognitive, technical, and behavioral skills
Facilitates multidisciplinary team training
Creates training opportunities for rarely encountered but highly challenging or risky situations
Provides structured learning opportunities with defined learning objectives
Can be scheduled at times convenient to trainees and instructors
Permits formal objective performance assessment
Facilitates use of debriefings as a source of detailed constructive feedback

Provides a very rich learning experience in a relatively short period of time
Optimizes use of time, money, and other resources

In 1999, the Institute of Medicine (IOM) published **To Err Is Human: Building a Safer Health System**, a report on human error and patient safety in the United States.[46] In this report, the authors estimated that between 44,000 and 98,000 Americans die each year as a result of medical errors. Although this figure has been highly debated, it is based on extrapolation of the data contained in studies out of Colorado, Utah, and New York published in peer-reviewed literature.10,55,69 The 1999 report was followed in 2001 by another from the IOM, Crossing the Quality Chasm: A New Health System for the 21st Century, in which the type of interventions, including training methodologies, necessary to improve patient safety were discussed.15 Subsequently in 2004, the Joint Commission (JC) published a Sentinel Event Alert describing ineffective communication as a major cause in almost 75% of the 47 cases of neonatal mortality or severe neonatal morbidity (lifelong serious neurologic compromise) reported to that agency; since that time, an additional 62 cases have been added.49 In response to these root cause analyses, the JC recommended that all health care organizations responsible for delivering newborns "conduct team training in perinatal areas to teach staff to work together and communicate more effectively" and "for high-risk events, such as shoulder dystocia, emergency cesarean delivery, maternal hemorrhage, and neonatal resuscitation, conduct clinical drills to help staff prepare for when such events actually occur, and conduct debriefings to evaluate team performance and identify areas for improvement."

The rationale for employing simulation-based learning in neonatal-perinatal medicine is clear. The management of serious neonatal pathology is one example of the classic low-frequency, high-risk event that lends itself well to simulation-based learning. Many health care professionals who care for newborns have the opportunity to manage serious or rare disease processes on an infrequent basis.[6,7] Even for those for whom a sufficient number of opportunities do exist, one must question whether it is acceptable to essentially practice on real living patients who are not capable of

providing informed consent on their own. Although parents do act as surrogate decision makers for children below the age of consent, few want to contemplate that their child will be the first one on whom someone will perform their first spinal tap, first intubation, or first thoracostomy tube placement. Therefore, it may be argued that the ethical imperative for simulation is stronger in pediatrics in general and in neonatal-perinatal medicine in particular than in any other field of health care.[14]

SIMULATION BASED RESEARCH

A systematic review by Issenberg highlighted that high-fidelity medical simulations (eg, simulators that change and respond to the user) are educationally effective and that simulation- based education complements medical education in patient care settings.[41] A recent systematic review and meta-analysis noted that compared with no intervention (eg, a control group or pre-intervention assessment), simulation-based training was effective in improving the knowledge, skills, and behaviors of health care professionals.[17] In pediatrics, simulation has been effectively used to teach neonatal[9,65] and pediatric resuscitation,[2,3,22] crisis resource management,[26,31,65] anesthesia,[48,63] procedural skills[5,49] (eg, gynecology examination, airway management), and surgical skills[36,54] (eg, endoscopy and minimally invasive surgery). Although the scope of simulation-based education in pediatrics is growing, few comparative studies have helped to clearly define the optimal instructional design features of effective pediatric SBEI.

The research agenda has clearly shifted from "if" simulation works to examining "who, what, when, where, why and how." Cook et al characterized features of effective SBEI.[16] However, a key question that remains largely unanswered for simulation educators is: How do SBEI need to be modified for different educational contexts? Comparative research is warranted to explore which instructional design features have the optimal impact for specific learning objectives, learner groups, and learning environments. Examples of comparative pediatric studies, using the various instructional design features as a framework, are described in Table 1.

Research using simulation as an investigative methodology leverages the standardization provided by simulation to answer diverse research questions that otherwise could not be answered feasibly, safely, ethically, or in a timely fashion in clinical settings. The simulated environment is used as an experimental model to study factors affecting human and systems performance in health care. Mannequin-based simulation has been particularly useful in this context. In this form, a mannequin connected to a computer that controls its vital signs and physical findings provides health care providers a realistic clinical experience. The use of mannequin-based simulation allows the researcher to have complete control over nearly every aspect of the clinical environment, including but not limited to the type, location, and size of equipment; the age and clinical status of the patient; and the composition, number, and experience of the health care providers.

SBR studies in this category can be grouped based on the performance-shaping factors that can enhance or degrade performance and subsequently impact patient safety and risk.[47] The various performance shaping factors that allow for a systematic approach to improving safety and error reduction in clinical medicine include (1) individuals (eg, fatigue, stress, experience), (2) teams (eg, team structure, communication), (3) work environment (eg, noise levels, resource availability), (4) technology (eg, use of clinical decision support or electronic health records), (5) systems factors (eg, work schedule and flow, policies, and procedures), and (6) patient factors (eg, clinical presentation).[47] By using simulation as an investigative methodology, investigators can systematically identify latent safety threats, test new technology and protocols, and improve the health care environment without any potential for harm to real patients. Lessons learned from research performed in the simulated environment can then be applied to the real clinical environment to optimize patient care processes and outcomes.

The use of SBR in pediatrics confers several distinct advantages. Unlike clinical research in which patient presentations are variable and unpredictable, SBR allows for standardized patient presentations that can be provided on demand. It is also permits the most important clinical variables, apart from the variable of interest, to be carefully controlled and accounted for. Standardization of the simulated environment for research can potentially be achieved provided the

research team has carefully accounted for the majority of the confounding variables (clinical diagnosis, clinical progression, etc). The authenticity of the simulated environment is particularly important when it is being used as a surrogate for the real clinical environment. Researchers should ensure that, to the best of their ability, all elements in the real clinical environment that could affect participant performance are also appropriately represented during the simulations.[47] Because it is not always possible to control every factor that could affect participant performance during a simulation (eg, institutional culture), optimizing authenticity in the environment can often be best achieved by using a real clinical space (eg, in situ simulation) to conduct the simulations. Another major advantage is that recruitment of individuals and/or teams of pediatric health care professionals can be scheduled according to convenience, thus allowing for more predictable recruitment. Additionally, there is no risk for patient harm when using simulation to test new technology, protocols, or clinical spaces, enabling the researcher to allow a study subject to make patient care errors, such that contributing factors can be fully observed and analyzed. Much like clinical research, SBR also has some challenges.

Research assessing the effectiveness of simulation as a training methodology shares similar design considerations with traditional research in medical education. In a recent article, Cook and Beckman outline important issues in designing experimental research in education.[15] One of the key issues they highlighted was the importance of describing both the educational intervention and the comparison group in sufficient detail to allow replication in other contexts. Thus, it is important to first address potential threats to the internal validity of traditional education research studies, such as subject characteristics, selection bias, history, instrumentation, testing, location, participant attitude, and implementation.[15] In addition, for research assessing simulation as a training methodology, several distinct elements of study design (ie, simulation-specific confounding variables), including simulator selection, scenario design, confederates, realism, debriefing, and video capture/review must be carefully controlled to mitigate threats to the internal validity of the research study.

Many of the same simulation-specific confounding variables described above may be important for research using simulation as an investigative methodology.

Additionally, these confounding variables are important in multicenter research studies in which standardization of the study protocol is of paramount importance (eg, high likelihood of variability between sites). These issues should also be carefully considered for SBR research in other potential study groups (eg, adult studies, interprofessional studies).

Because several options for infant and pediatric simulators exist, researchers must consider the functionality and features of the simulator when designing the study. The functionality of commercially available infant and pediatric simulators is highly variable, with differences in their ability to simulate eye opening and closing, location and quality of pulses, size and compliance of lungs and chest, and design and anatomy of the airway. Studies using scenarios and mannequin-based simulation may require a certain level of functionality and realism to accurately simulate a certain medical problem. For example, if a study is designed to assess the impact of a real-time feedback device on the depth of chest compressions, it would be important to select a simulator which, at a minimum, allows for chest compressions to a depth greater than that required by resuscitation guide- lines (eg, at least 5 cm for children or adults). Similarly, a study to assess the impact of a trauma checklist on the management of head injury requires a simulator that could mimic deterioration in level of consciousness in which the eyes are able to open and close and pupils can react to light. Failure to consider the functionality of the simulator may influence the relevance and accuracy of the study outcomes. If a particular function is crucial to the study, it should be mentioned in the methodology prominently. The most logical strategy would be to choose the same simulator with all of the desired functionality for all research sessions. For multicenter research, this may have resource implications if not all sites have the desired simulator available, that is, some sites may not be able to enroll subjects if the required simulator is integral to the study design and cannot be made available to them.

For either type of SBR, scenarios should be developed that can be delivered in a uniform fashion from participant to participant, group to group, and, if multicenter, from institution to institution. For

example, a research study to test the impact of an SBEI on management of pediatric anaphylaxis requires the scenario be standardized in a fashion that will ensure each group of participants is exposed to a case of similar difficulty, with similar challenges in decision-making and clinical care. Allowing too much variation in case delivery would change the intervention of interest or add unnecessary confounders. To ensure scenarios are delivered in a standard fashion, researchers can consider various strategies, the selection of which is dependent on the research question, goal of the study, participant characteristics, and outcome measures: (1) control the duration of the scenario by limiting the overall time (ie, scenario is stopped at a certain time independent of participant actions/interventions) and/or setting transitions from one clinical state to the next at predefined times, independent of subject interventions (eg, normotensive to hypo- tensive at 5 minutes). Doing so allows researchers to see if certain tasks are done in a predefined time frame, with the benefit of standardizing scenario duration. The unfortunate consequence of this strategy is that sometimes conceptual realism is sacrificed (eg, patient spontaneously converts from ventricular tachycardia to sinus rhythm without intervention). (2) Alternatively, researchers can control the responses of the simulated patient by setting transitions from one clinical state to another based on subject interventions and independent of time (eg, blood pressure changes from normotensive to hypotensive if 20 mL/kg normal saline fluid bolus is not given in the first 5 minutes). Doing so allows clinical progression based on participant interventions (ie, high conceptual realism), but the downside is that the duration of the scenario may be highly variable from group to group. (3) Finally, researchers can control confederate behaviors by clearly standardizing verbal, audio or visual cues that are provided to confederates and faciliators (eg, capillary refill, level of consciousness). These cues can be tied to participant actions/inaction, patient transitions in physiology, or certain time points in the scenario. During SBR, improvisation must be minimized for confederates and facilitators and only used to maintain standardization and realism of the scenario. Careful review of the scenario template and training of scenario facilitators is recommended to establish reliability. Pilot testing scenarios before starting a research study will help investigators identify and correct potential pitfalls before enrollment begins. This is particularly important for

multicenter research, in which sites will be using different re- search coordinators. Pilot testing provides an opportunity to train research. facilitators ahead of time and for the re- search team members to share their experiences and struggles and offer suggestions for streamlining the research process. Sharing videos of pilot runs (both successes and failures with descriptions of lessons learned) allows sites to have a shared mental model of exactly how the scenarios should be managed.

Confederates, or actors, can be used in SBR to increase realism and help create and/or manipulate a situation for study purposes. In adult studies, confederates are used in the role as members of the health care team or as the patient. In pediatric research, confederates can be integrated into the simulated environment as family members or caregivers to enhance pediatric-specific aspects of clinical care, or children (in selected circumstances) can be recruited as confederates to play the role of the sick patient. In contrast to adult studies, the use of real children to play the role of a sick patient may be at times impractical (or impossible) because younger children as less likely to adhere to the predefined confederate role or are unable to reliably reproduce desired physical findings (eg, tachypnea). This limitation creates an exaggerated reliance on simulation technology in pediatrics. As such, the pros and cons of using a child as a confederate should be carefully weighed, and the relative benefits of using a simulator as the patient should be considered before making a final decision. As an example of how confederates may be used in research, an SBEI may be used to teach residents how to communicate with family members, and confederates could be scripted to play the role of parents who are interacting with the participants. The use of confederates requires careful scripting of confederate roles, which can be tailored to address the research question (eg, issues of health literacy, culture factors in pediatrics, delivering bad news). Unfortunately, no research to date has described the ideal way to train confederates for SBR, although there are descriptions of multiple methods used in a single study.[43] Strategies that can be used to orient confederates to their roles include the following: (1) development of a scenario script or template with detailed description of confederate roles, (2) confederate cue cards that can be used as a quick reference during the scenario, (3) confederate training video with expert modeling of desired

confederate actions, and (4) confederate training session with pilot research sessions prior to initiation of the study. During pilot sessions, investigators will be able to see how participant and confederate behaviors tend to deviate from expected, thus allowing time to revise the study protocol and supporting materials to be more resilient to the variability associated with human actors and participants. Careful consideration of strategies to standardize confederate behaviors in multicenter research is particularly crucial; individuals selected to be confederates may differ in background, experience, and expectations.

Several ways of categorizing simulation fidelity or realism have been described.[21,43] Although the impact of realism on the quality of simulation-based pediatric education is controversial,[10,23] investigators should be attentive to the importance of realism when running simulation scenarios for research purposes. Enhanced levels of realism help to immerse participants in the simulated experience, whereas a lower level of realism may lead to disengaged participants. A variable level of realism from scenario to scenario can introduce a confounding variable that may potentially affect the way individuals or teams perform. When designing a scenario for SBR, there are 3 important components of realism to consider.[22,60] "Physical realism" refers to the physical properties of the simulation mannequins and environment used to run the scenario. Standardizing the environment involves providing the same equipment and human resources, as well as positioning the equipment in the same location to which the participants are accustomed and in the same fashion for all participants. While doing so may help to achieve standardization among groups and/or sites (eg, in a multicenter study), it may also systematically introduce a bias that favors participants from one institution where, for example, the resuscitation cart is placed in the exact spot they are used to in the real clinical environment. Furthermore, replicating certain noises or distractors (eg, phone call or page) typically found during real patient care may help to promote standardization but also inadvertently introduce a confounding variable (eg, one institution typically has less ambient background noise compared with another). As such, while researchers attempt to achieve complete standardization of the physical environment, they must also consider the introduction of confounding variables when doing so. One effective strategy is to orient all subjects to the features

of the simulator and the physical environment and effectively removing unfamiliarity with the simulator or space as a potential confounder. This can be achieved by providing a scripted orientation to the research environment. "Conceptual realism" refers to the theory, meaning, concepts, and relationships attached to each simulated scenario.[60] Specifically, conceptual realism involves clinical authenticity with "if–then" relationships presented during the simulation,[60] such as, "If fluid is given for hypovolemic shock, then the blood pressure should increase." A consistent degree of conceptual realism relies heavily on carefully designed scenarios and facilitators who are familiar with the scenario. Finally, "emotional realism" relates to the feelings that are evoked in subjects as a result of participating in the simulation.[60] Managing the degree of emotional realism in subjects can be difficult but is especially important when individual or team performance is an outcome measure. The degree and nature of interaction between subjects and confederates can often have a strong impact on emotional realism (eg, a confederate playing the role of a parent starts crying during the scenario in an unscripted manner); this must be understood by research confederates, who should be carefully scripted in the manner described earlier.

Studies assessing the efficacy of simulation as a training methodology should carefully consider the relative value of debriefing as part of the overall learning experience.[41] Conversely, many studies using simulation as an investigative methodology may not involve debriefing at all. Although debriefing has been characterized as the most important element of simulation-based education, failure to standardize the debriefing introduces a major threat to the validity of any SBEI. A recent review of the debriefing literature outlined the key characteristics of debriefing as *the 5 Ws* of debriefing research: who (debriefer characteristics), what (content and methods of debriefing), when (timing), where (environment), and why (theory).[57] Each of these debriefing characteristics should be carefully standardized and reported when assessing simulation as an educational intervention. For example, if using multiple debriefers in a study, each debriefer should have the same level of expertise and should be trained to use the same method of debriefing. This is particularly crucial when 1 element of the debriefing is the intervention of interest in the study.

Standardization of the other debriefing characteristics will allow for isolation of the specific debriefing variable (eg, location of debriefing: in resuscitation room vs in separate debriefing room). Many SBR studies use video to capture individual or team performance and then rate the videos using assessment tools as an outcome measure.[10] Using video in this manner requires the researcher to consider the ideal video angle(s) and the number of views required for capturing the desired behaviors. Similarly, microphone placement and audio interference are important, particularly for studies focusing on communication. Researchers should also consider whether the vital signs monitor display is a necessary as an adjunct to the video views for raters.

Improperly or inadequately captured video or audio can hinder the rater's ability to accurately score performance. This should be accounted for when calculating the sample size for studies required video capture and review. In multicenter studies in which video capture hardware and software varies from site to site, there is a greater need to standardize the methods of video capture and account for dropout related to technical issues when calculating sample size. On the basis of our collective experience in conducting SBR with video review, we have occasionally lost up to 10% of video because of issues with poor camera angle, sound quality, or problems with technology. As such, we recommend including video capture and review as part of the pilot testing process in which pilot videos are reviewed for quality (ie, video, audio, and camera angle). Also consider increasing your sample size a priori to account for lost video; however, it will be important to assess whether there is any systematic bias to the lost videos.

The selection of outcome measures for SBR primarily depends on the research question. One should choose outcome measures that are relevant, measurable, and hold a plausible association to the intervention. Outcomes for both types of SBR may be framed based on Kirkpatrick's hierarchy of evidence, with learner's attendance at the base of the pyramid (eg, satisfaction); knowledge, skills, and attitudes of participants in the middle; and behavior change and clinical outcomes in respectively higher positions.[45] Satisfaction data are easier to capture but less impactful than evidence of actual process of care or patient improvements based on the intervention. In quantitative SBR, methods to measure outcomes most commonly fall within 1 of 3

categories: (1) the simulator itself as a measurement tool, (2) observational checklists, and (3) clinical and/or translational outcomes. We focus our discussion on these 3 categories as they pertain to pediatric simulation research.

Most pediatric simulators are able to measure and record specific data points related to the passive physio- logic state of the simulator as well as the actions performed on it by participants. These provide objective measurements (eg, timing of head tilt, chin lift, or pulse check; depth and rate of chest com- pressions) that can be exported into a research database for analysis. Several studies have leveraged the simulator's ability to precisely capture time to study an intervention's impact on time to performance of a skill or procedure.[58,62] As technology evolves, so will the ability to collect and store various types of data in usable formats for research.

One potential pitfall to using simulation technology to measure outcomes is that the accuracy of certain measurements is largely unknown. For example, some simulators can provide detailed logs of how deeply chest compressions are performed. However, information about precision or validity of this measurement is unknown. For example, if a study is measuring depth of compressions as the main outcome measure, how does the researcher know if the compliance and depth of the simulator chest wall matches that of a live infant or pediatric patient? More research is needed to validate proxy measurements from simulators in the clinical world. Industry partnerships can help to address some of these limitations. In the meantime, it is important for the commercial simulation and research community to collectively explore and document the validity and reliability of these features.

Observational checklists are often used to assess technical skills, behavioral performance, and/or clinical performance in SBR studies.[3,10,23] Discussion on validation and psychometrics are outside the scope of this review, but researchers should ensure that the assessment tools used are reliable and valid for the study population and specific context of interest. Simply using a published checklist may not be sufficient, and pilot studies to assess the checklist can improve the rigor of the study. One of the advantages of simulation is the ability to control for other variables and measure a person's performance on a standard model and setting. The choice of checklist will

depend on the specific study objectives, along with the relative strengths and weaknesses of each checklist. Several observational checklists for pediatric care have been developed and validated in a simulated environment.

If observational checklists are used as an outcome measure, the researcher can apply the tool in real-time and/or retrospectively by video review. Real-time review allows for rapid acquisition of data. However, reliability of data collected in real-time is highly dependent on rater familiarity with the tool and the ability of the rater to accurately assess performance in real-time while concurrently recording scores. Conversely, video recording allows reviewers to pause, rewind, or repeatedly review performance to more thoroughly extract objective details. Use of video also allows the researcher to more easily blind the rater to study purpose or group allocation. Our research network has leveraged technology to share videos online and therefore make available to a large group of raters.[11] Regardless of whether real-time and/or recorded review is used in a study, the implementation of a rater training process before the study will help to improve interrater reliability.[10]

The ultimate measure of any medical intervention is how it affects patient care and clinical outcomes. This is particularly important because it is unclear the degree to which selected human performance measures in a simulated environment (eg, observational checklists) correlate with true patient and/or health care outcomes. Because of the size and cost of conducting such studies with real patient outcomes, there are far fewer examples of SBR measuring clinical outcomes. In Cook's meta-analysis of 609 technology-enhanced simulation articles, only 32 studies reported patient/ health outcomes.[17] In a recent study,[2] Andreatta demonstrated improved survival rates from pediatric cardiac arrest after implementing a longitudinal simulation code program. Studies like this are especially challenging because there are typically numerous confounding variables that have an impact on clinical outcomes, and learner groups have other sources of learning outside of the study intervention. In an attempt to address these challenges, several groups have begun to form longitudinal data- bases to measure the impact of educational interventions over time (eg, the American Heart Association's Get With the Guidelines—Resuscitation registry). A multicenter pediatric network, the International Network for Simulation-based Innovation, Research and

Education (INSPIRE, http://www.inspiresim.com) has been formed to help achieve the sample size and power needed to measure more infrequent clinical outcomes. These initiatives have the potential to facilitate the incorporation of clinical outcomes into future pediatric SBR studies.

2.0 PERSONAL CONTRIBUTIONS

Submitted manuscripts

- **Binotti M**, Genoni G, Rizzollo S, Carenzo L, Monzani A, Ingrassia PL. Simulation- based medical training for paediatric residents in Italy: a nationwide survey. Submitted to BMC Medical Education in September 2018.
- Cavallin F, **Binotti M,** Ingrassia PL, Genoni G, Rizzollo S, Monzani A, Trevisanuto D. Impact of a mobile application for heart rate assessment in simulated neonatal resuscitation: a randomized controlled crossover study. Submitted to Arch Dis Child Fetal Neonatal Ed in November 2018.

Oral communication

- G. Genoni, S. Rizzollo, L. Carenzo, M. De Luca, G. Bona, F. Ferrero, P.L. Ingrassia, **Binotti M**. Assessment of newborn resuscitation skills: a pilot study among paediatric residents using high fidelity simulation. 23nd Annual Meeting of the Society in Europe for the Simulation applied to Medicine, Paris: 14-16 June 2017.

Indexed publications

- **Binotti M**, Cavallin F, Ingrassia PL, Pejovic NJ, Monzani A, Genoni G, Trevisanuto D. Heart rate assessment using NeoTap Advanced Support: a simulation study Arch Dis Child Fetal Neonatal Ed 2018;0:F1–F3. doi:10.1136/archdischild-2018-315408
- **Binotti M**, Genoni G, Carenzo L, Ferrero F, Bona G, Ingrassia PL. Common Complication of Sickle Cell Disease in a Resource-Constrained Environment: A Simulation Scenario. Simul Healthc. 2017 Aug;12(4):274-278.

Simulation-based medical training for paediatric residents in Italy: a nationwide survey

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Abstract

Background: A prompt start to an appropriate neonatal and paediatric resuscitation is critical to reduce mortality and morbidity. However, residents are rarely exposed to real emergency situations. Simulation-based medical training (SBMT) offers the opportunity to improve medical skills in a controlled setting. This survey describes the current use of SBMT by paediatric residents in Italy with the purpose of understanding residents' expectations regarding neonatal and paediatric emergency training, and identifying gaps and potential areas for future implementation.

Methods: A survey was developed and distributed to Italian residents. SBMT was defined as any kind of training with a mannequin in a contextualised clinically realistic scenario, excluding international standardised courses.

Results: The survey was completed by 274 residents. Among them, 88% stated that they received less than 5 hours of SBMT during the 2015-2016 training year, with 66% not participating in any kind of simulation activity. In 62% of the programmes no simulation training facility was available to residents. Among those who received SBMT, 46% used it for procedures and skills, 30% for clinical scenarios, but only 24% of them reported a regular use for debriefing. Of the overall respondents, 93% were interested in receiving SBMT to improve decision-making abilities in complex medical situations, to improve technical/procedural skills, and to improve overall competency in neonatal and paediatric emergencies, including non-technical skills. The main barriers to the implementation of SBMT programmes in Italian paediatric residencies were: the lack

of experts (57%), the lack of support from the school director (56%), the lack of organisation in planning simulation centre courses (42%) and the lack of teaching materials (42%).

Conclusions: This survey shows the scarce use of SBMT during paediatric training programmes in Italy and points out the main limitations to its diffusion. This is a call to action to develop organised SBMT during paediatric residency programs, to train qualified personnel, and to improve the quality of education and care in this field.

Keywords: simulation, simulation-based medical training, survey, paediatrics, residents

Background

Simulation-based medical training (SBMT) has been defined as the artificial representation of a complex real-world process with sufficient fidelity with the aim to facilitate learning through immersion, reflection, feedback, and practice minus the risks inherent in a similar real-life experience [1]. It is mainly based on the use of mannequins as an alternative to real patients, allowing for the creation of realistic but well-controlled clinical settings that simulate real-life patient care. The efficacy of SBMT as a teaching method for paediatric education has been assessed in a recent meta-analysis [2]. In addition, a recent Cochrane review has shown the importance of SBMT in neonatal resuscitation programmes to reduce newborn mortality and morbidity [3]. In fact, SBMT is a useful tool both to teach skills and to assess their acquisition by residents. Many studies have shown that paediatric residents' resuscitation skills are inadequate, with little improvement during residency [4,5]. These findings suggest that it is insufficient to rely on direct clinical exposure alone to achieve the requirements for emergency care skills [6]. Conversely, SBMT has been associated with improvement in key measures of quality life support and progressive acquisition of resuscitation skills during paediatric training [5]. Furthermore, SBMT is also an effective method to teach non-technical and behavioural skills such as teamwork, leadership, communication and role clarity [7]. Moreover, some paediatric milestone competencies are difficult to assess using traditional methodologies. SBMT meets the needs of programme directors to acquire measurable

learning outcomes on their trainees' performances [8]. For these reasons, the use of SBMT in paediatric residencies has grown over the past decade. In U.S. and Canadian paediatric emergency medicine, SBMT was integrated into the resident curricula being provided by 97% of fellowship programmes in the 2011-2012 academic year [9]. Recent surveys showed that SBMT is used by more than 90% of U.S., Canadian and English-language-based emergency medicine residency programmes, even though a considerable variability in the accreditation and certification, and frequency and timing of SBMT has been highlighted [10,11].

Conversely, up until recently, the use of SBMT was scarce in European paediatric fellowships. In 2009, only 3 Swiss paediatric healthcare institutions used SBMT [12], rising to 20/30 (66.6%) paediatric hospitals and healthcare departments offering SBMT in 2015 [13].

The aim of this study is to describe, using a bottom-up approach, the current use of simulation in paediatric residency programmes in Italy, in order to understand the expectations of fellows with regard to neonatal and paediatric emergency training, as well as to identify gaps and potential areas for future implementation.

Methods

Survey development and content

A 40-item survey was developed by simulation experts from two Italian simulation centres, SIMNOVA (Novara) and SimMeyer (Florence). The questionnaire was composed of multiple choice questions and questions in which participants rated their agreement on a 10-point Likert scale (1=strongly disagree – 10=strongly agree).

For the purpose of this survey, SBMT was defined as any kind of training for healthcare providers using a mannequin in a contextualised clinically realistic scenario. Traditional international courses, such as Paediatric Advanced Life Support, European Paediatric Life Support, Neonatal Life Support, Advanced Trauma Life Support and Basic Life Support, were excluded from SBMT

definition because these formats do not include the use of technical equipment or the environmental and psychological elements of SBMT. The survey included questions evaluating: the degree of interest toward simulation, the current use of SBMT, the availability of facilities and support resources in Italian paediatric residency programs, the benefits of simulation perceived by paediatric residents and potential barriers limiting its current use.

Survey dissemination

The survey was disseminated to all the 35 Italian paediatrics residency programme directors, asking them to distribute it among their respective trainees. The survey was also available on a web-based survey tool (www.surveymonkey.com; SurveyMonkey, Inc, Palo Alto, CA) for 12 months from the 1st April 2016 to the 1st April 2017. Moreover, it was directly disseminated by the National Observatory of Paediatric Residents (ONSP) via its official website page and three consecutive newsletters. In addition, a paper copy of the survey was delivered to the participants of two national events: the 2016 ONSP National Congress in Bologna and the Paediatric Simulation Experience 2016 in Novara. It was possible to answer the web-based survey only once, and in the questionnaire's written instructions, respondents were asked to answer only once.

Responses to the survey were anonymous and data were collected and presented in aggregate form. Completion of the study questionnaire implied participant consent. According to the published guidelines of the British Educational Research Association (BERA), surveys do not require approval by an ethical review board [14].

Results are presented as number (percentage) for discrete variables or as median and interquartile range (IQR) for continuous variables, as appropriate.

Results

Study sample

A total of 274 questionnaires were returned, out of 1900 Italian paediatric residents. Respondents were from 25 out of 35 Italian paediatric residencies (71%), with a median of 7 respondents per residency (min 4 – max 11), from different geographical areas: Northern Italy (47%), Central Italy (22%) and Southern Italy (31%). Respondents were attending the first, second, third, fourth and fifth years of residency programmes in 12%, 22%, 21%, 26% and 19% of cases, respectively.

Simulation exposure

In the 2015-2016 academic year, 88% of respondents spent less than 5 hours in SBMT, with approximately 66% not participating in any kind of simulation activity (figure 1). 29% of respondents reported that their residency programmes offered SBMT as a support for teaching neonatal and paediatric emergency care. SBMT was used for the assessment of resuscitation skills in 15% of residents. 22% had attended simulation courses organised by other schools. The reported SBMT programmes were focused on elements of procedural training (46%) and, to a lesser extent, on the creation and development of scenarios (30%), and debriefing (24%). Only 5% of respondents had been trained in teaching the use of simulation and only 1% had done research in this field.

Table 1 shows the method used to teach technical skills during paediatric residency. Compared to bedside practice and other teaching methodologies like frontal lessons, SBMT was the preferred method used to teach chest compressions (45%), cardioversion/defibrillation (36%), endotracheal intubation (33%), difficult airway management (21%) and intraosseous access (30%).

Table 1: Technical skills' teaching methods reported by the 274 respondents to the survey.

	SBMT	**Bedside**	**Other methods**	**Not taught**
Mask ventilation % (n)	29% (79)	33% (90)	11% (30)	27% (75)

Endotracheal intubation % (n)	33% (90)	19% (52)	6% (17)	42% (115)
Difficult airway management % (n)	21% (58)	7% (20)	5% (13)	67% (183)
Chest compressions % (n)	45% (124)	17% (47)	6% (16)	32% (87)
Cardioversion/defibrillation % (n)	36% (99)	3% (8)	3% (8)	58% (159)
Central venous access % (n)	6% (17)	24% (67)	4% (11)	66% (180)
Umbilical venous access % (n)	9% (25)	54% (148)	7% (19)	30% (82)
Intraosseous access % (n)	30% (82)	7% (19)	3% (8)	60% (165)
Lumbar puncture % (n)	7% (19)	39% (107)	16% (43)	38% (105)
Chest tube placement % (n)	8% (23)	12% (32)	9% (25)	71% (194)

Simulation facilities and resources

In 62% of residency programmes, there was neither a simulation-training centre nor an affiliation with another institution's simulation centre. In schools with or affiliated with simulation facilities, the laboratory was easily accessible, either located in the same building (74%) or in another building within a 5-10-minute walking distance (19%) from the department, or reachable by public transport or car (7%). In 66% of cases, existing laboratories were made up of just a simulation room. In the remaining cases, the simulation centre also consisted of a control room (38%), a debriefing room (32%), multifunctional rooms with audio-visual capabilities (23%) and other rooms (34%). However, even where a laboratory was available, a lack of support personnel was reported in 53% of questionnaires. Where present, the staff consisted of healthcare professionals such as doctors, nurses or postgraduates who coordinated simulation activities (69%), simulation instructors (18%) and other personnel (13%). Regarding the available equipment, 24% had low-fidelity mannequins, 22% used high-fidelity neonatal and paediatric mannequins, and 54% did not know. Regarding funding sources for simulation, 12% reported that the funds came from the university, 28%

answered that there are no available funds dedicated to SBMT and 60% did not know where funding came from.

Perceived benefits of SBMT

The perceived preparation of residents to effectively manage paediatric and neonatal emergencies expressed as median was 4 (3-6) and 5, respectively. The interest for SBMT was high (93%). When asked about perceived benefits of SBMT, 99.6% of respondents stated that it is helpful in improving decision-making abilities in complex situations; 99.3% agreed that it is helpful in improving technical/procedural skills; 99.6% agreed that, overall, it is an effective tool to improve neonatal and paediatric emergency medicine competence; and, finally, 97.4% agreed that it is a valuable tool for non-technical skills such as leadership, communication and team management.

Barriers to the use of SBMT

The main barriers to the implementation of SBMT programmes in Italian paediatric residencies were: the lack of experts (57%), the lack of support from the school director (56%), the lack of organisation in planning simulation courses (42%), and the lack of teaching materials (42%).

The main limits to external course participation were: costs related to external training, including travel and accommodation (73%), lack of time (54%), and the unavailability of SBMT courses nearby (29%).

Discussion

This survey represents a faithful and realistic snapshot of SBMT in Italy, involving 71% of paediatric residency programmes and including paediatric residents from the whole country. Our survey reveals the scarce use of SBMT during paediatric training in Italy. Two thirds of respondents did not participate in any kind of simulation activity during the previous academic year, and the majority of programmes did not implement neonatal and paediatric emergency training with SBMT. These

data contrast with the current situation in other developed countries, such as the U.S., Canada and Switzerland, where SBMT has been implemented into educational curricula and offered by the majority of paediatric residency programmes, even though great differences between various countries in terms of SBMT's accreditation, frequency and timing are still reported [9-11,13]. Increasing evidence suggests that SBMT improves healthcare education, practice and patient safety, allowing learners to achieve competence without putting patients at risk. The literature suggests that simulation in medical education improves both technical and non-technical skills [3,5,7,15]. Regarding technical skills, the learning of some procedures is a crucial component of paediatric education, and it represents an accreditation requirement for paediatric training programmes in Canada and Australia [16,17]. Furthermore, in 2007, the U.S. Residency Review Committee published a list of procedures and skills in which residents should have "sufficient" experience [18]. In Italy, every paediatric residency has its own training objectives, including a list of procedural skills that residents need to acquire. In this study, we show that SBMT is mostly used for this purpose. However, as shown by others and us, training for some important neonatal and paediatric emergency care procedures (like positioning of thoracic drainage and central venous access or management of difficult airways), is often not provided. As a result, a large percentage of residents fail to achieve procedural skills competence [19]. This highlights a weakness in Italian paediatric education and should be considered as a starting point to improve the quality of training programmes and, finally, the expertise of future paediatricians. From this perspective, simulation is an ideal method, on the one hand, to learn these skills by integrating the possibility of direct observation, frequent practice and feedback, and, on the other hand, to objectively evaluate the achievement of these competences. Studies using simulation task trainers to teach paediatric residents procedures, such as central venous catheter, chest tube insertion and endotracheal intubation, show improved performance, demonstrating that simulation is an effective educational tool [20-23]. Furthermore, studies have shown that the majority of paediatric residents have an insufficient knowledge and experience in the care of critically ill children due to their low exposure to such conditions [24,25]. It has been previously reported that simulation can improve paediatric

residents' performances during high-risk situations like cardiopulmonary arrest and paediatric trauma [26-29].

Another crucial component of SBMT is the acquisition and improvement of non-technical and behavioural skills, such as teamwork, leadership, communication and role clarity [7]. However, from this survey, this aspect seems of secondary importance in Italian paediatric education, and this highlights another important gap that urgently needs to be addressed. Indeed, some "high-impact" conditions, like neonatal and paediatric resuscitation, besides being rare conditions, usually involve multidisciplinary teams, like paediatricians and anaesthesiologists, and improving communication and teamwork may lead to a better patient outcome.

Despite the low diffusion of SBMT in Italy, paediatric residents show an extremely high interest in acquiring basic knowledge of SBMT. They perceive its potential key benefits to improve decision-making abilities in complex medical situations and to learn technical/procedural and non-technical skills. The apparent discrepancy between the high perceived benefit of SBMT and actual resident exposure to SBMT may be explained by what residents know from literature data or from other residents' experiences, and by what they have personally experienced during courses like Paediatric Simulation Experience, outside their residency programmes [30]. Italian residents identified the lack of paediatric simulation educators, the lack of support from the school director and the lack of organisation in planning simulation courses and teaching materials as the main barriers for the development of SBMT. To counteract these problems, along with the growing interest in SBMT, some Italian simulation centres offer courses for residents like Paediatric Simulation Experience developed by SIMNOVA (Novara) and SimMeyer (Florence) [30]. However, there are some limitations to external course participation, such as cost and distance. In Switzerland, during the last few years, a significant surge in the use of SBMT has been shown, increasing from 3 institutions in 2009 to 20 out of 30 institutions in 2015 [13]. The majority of units offered SBMT in an in-situ setting, and this could limit costs relating to the creation of a simulation

centre in those hospitals that do not already have one. Furthermore, more than one residency school can aggregate in a single simulation centre to limit costs and the need for personnel.

It is of importance to develop a “simulation culture” among educators and residents to improve the quality of paediatric emergency practice and therefore the management of patients and their outcomes. Moreover, SBMT is an instrument for the objective evaluation of technical and non-technical skills, and a promising field of research.

Limitations

Our study had several limitations. Despite efforts to boost participation, the sample size was quite small. However, this study covered 71% of training programmes in Italy, equally distributed throughout the country, and this is the first comprehensive description of the current use of simulation in paediatric residencies in Italy. In addition, a selection bias cannot be excluded, as residents who were more interested in the topic were probably more likely to reply. Another limit of this study is that about one third of the respondents were from the first two (of five) years of residency. However, in Italy, SBMT is not scheduled at a fixed point in time during residency programmes.

Conclusions

In conclusion, this survey reveals the scarce use of SBMT by Italian paediatric residency programmes and points out the main barriers that prevent SBMT diffusion. This is a call to action to develop organised SBMT during paediatric residency programmes, to train qualified personnel and to carry out research in this field in order to improve the quality of education and care.

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COMMON COMPLICATION OF SICKLE CELL DISEASE IN A RESOURCE-CONSTRAINED ENVIRONMENT: A SIMULATION SCENARIO

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CASE INFORMATION

Demographics

Module Title: General Medicine/Pediatrics in low-resource settings

Case Title: Common complication of sickle cell disease in a resource-constrained environment

Patient Name: Bakari Myovela

Simulation Developers: Marco Binotti, Giulia Genoni, Luca Carenzo

Dates of Development: June 2015

Appropriate for the Following Learning Groups:

- Physician in training to operate in a low-resource environment;
- Paediatric residents and fellows;
- Anaesthesia residents and fellows;
- Intensive Care residents and fellows;
- Emergency Medicine residents and fellows

Specialties: general medicine/ paediatrics/anaesthesiology/intensive care.

CURRICULAR INFORMATION

Educational Rationale

This case provides an opportunity to learn and discuss the management of a paediatric patient with sickle cell disease (SCD) and acute chest syndrome (ACS) in a low-resource setting.

SCD is among the most common monogenetic diseases worldwide, especially in sub-Saharan Africa where it represents a real public health hazard (236.000 born/year)[1].

ACS is an acute lung injury syndrome that occurs frequently in patients with SCD. It is the second most common cause of hospitalization, and the leading cause of 25% of SCD-related mortality, especially in children[2]. Over the last decades, humanitarian crises have seen a sharp upward trend. Regrettably, physicians involved in humanitarian actions in resource-constrained settings have often demonstrated incomplete preparation for these compelling events which have proved to be quite different from their daily work[3-4]. This case requires a prompt diagnosis of ACS and a timely management of the condition despite non-technical difficulties related to communication with parents and technical difficulties caused by limited medical staff and equipment. This scenario emphasizes and requires the learner to identify the cause of respiratory insufficiency in a 3-year-old child and manage respiratory support, fluid infusion, fever, analgesia, and eventually transfusion. This scenario is based in a real case occurred during a field mission of one of the authors and has been developed in an attempt to enhance participants awareness on the need to

receive proper training before deployment and to evaluate their crisis resource management skills in an unfamiliar and under-equipped environment.

Learning Objectives:

(1) Patient care (PC), (2) medical knowledge (MK), (3) practice-based learning and improvement (PLI), (4) interpersonal and communication skills (CS), (5) professionalism (PR), and (6) systems-based practice (SBP).

1. Discuss the differential diagnosis for respiratory insufficiency in a paediatric patient (PC, MK).
2. Collect from the mother much information as possible about the past history of child, despite cultural and language difficulties (CS).
3. Describe the diagnosis and treatment of ACS (PC, MK).
4. Diagnose and treat ACS with limited equipment (PC, MK, PLI).
5. Discuss how to prioritize tasks and delegate tasks in a in a low-resource setting (PC, CS, PLI, SBP).
6. Evaluate the risks and benefits of endotracheal intubation and blood transfusion (PC, MK).
7. Mobilize and use stuff in an unfamiliar resource-constrained environment (CS).
8. Demonstrate ability to interact effectively and respectfully with the local staff (CS, PR).

Guided Study Questions:

1. What are the causes of respiratory insufficiency in a 3-year old child with SCD?
2. How do you diagnose and treat ACS with limited medical equipment?
3. How do you manage respiratory support and anaemia?

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PREPARATION

Monitors Required

a. Manual Noninvasive blood pressure (NIBP) cuff

b. Pulse oximeter

Other Equipments Required

a. Patient simulator (we used SimBaby, Laerdal, Wappingers Falls, NY)

b. Oxygen tank

c. Endotracheal tube

d. Laryngoscope

e. Self inflating ambu bag

f. Nasal prongs

g. Intravenous (IV) normal saline and giving sets, IV cannulas

h. Drugs: antibiotics (ampicillin, gentamicin, ceftriaxone), paracetamol, ketamine, diazepam, salbutamol

i. Packed red blood cells

Supporting Materials

• Chest x-ray

• Labs:

CBC: WBC 15.4 X 10^9/L, neutrophils 74%, lymphocytes 22%, Hb 50 g/L, Hct 0.228

Malaria Quick Test: Negative

Time Duration

Set-up: 15 minutes.

Preparation: 10 minutes.

Simulation: 15 minutes.

Debrief: 30 minutes.

CASE STEM

You are a medical doctor taking part in a humanitarian mission in a peripheral hospital in Akonolinga, Cameroon, a sub-Saharan African country. You are visiting outpatients. A mother brings her 3-year-old child for fever, cough and breathing difficulty. A local nurse is in the room with you (English and local language speaking).

Background and briefing information for Facilitator/coordinator's eyes only:

Participant is handed over the case of a 3-year-old child brought by the mother for fever, cough and breathing difficulty. No past medical history is known other than the child has received in the past several blood transfusions for an unknown reason. Of course the reason is known to the instructor, and is that the child is presenting with a severe complication of sickle cell disease, however this is not known by the little patient mother which is presenting the case to the participants. Moreover blood transfusion should be reported only during history taking and not disclosed openly if not specifically questioned. No clinical documentation is available. The patient is irritable and shows tachypnea, dyspnea and wheezing. He rapidly progresses to respiratory failure. No ventilator nor intensive care facility is available in Akonolinga hospital. The learner should decide whether to intubate, to ventilate with ambu bag and to transfer the patient in a larger hospital (time of transport: 3 hours, transport cost for parents: 550 US dollars; 333590 Central African CFA Franc) or to use oxygen delivered with nasal prongs and follow a more conservative approach[5-7]. Following primary evaluation a basic blood count can be requested. The child shows severe anaemia (Hb 50 g/L). A blood transfusion is indicated, so the participant will have to decide whether he wants to transfer the child or not[8]. Malaria can be excluded by means of rapid strip test which should be requested by scenario participants (Basic Blood Test and Malaria quick test are the only laboratory tests available at this facility).

Other reasonable interventions will include the administration of empiric antibiotic therapy (i.e. ceftriaxone), analgesic (paracetamol), bronchodilators[5-7]. An adequate fluid support can be started[5-7]. Finally, a diagnosis of ACS can be made. In this setting, with no microscope or staining available, Sickle Cell Disease can only be a presumptive diagnosis.

The scenario starts with the learner accompanied by a local nurse. The local nurse speaks both english and the local language, while the patient mother only speaks the local language. The participant should maximise the help of this nurse in communicating with the mother both for history taking and to inform the mother about the patient's clinical conditions. The participant should discuss with the mother about the decision to intubate the patient and about risks/benefits ratio and cost of a transport and blood transfusion[9].

PATIENT DATA, BACKGROUND AND BASELINE STATE

Patient History

You are visiting outpatients with a local nurse. A mother brings her 3-year-old child for fever, cough and breathing difficulty from 2 days. The mother speaks only the local language.

Bakari is underweight (weight, 10 kg).

Review of Systems

Central nervous system: Alert, irritable.

Cardiovascular: Tachycardia, systolic murmur 3/6.

Pulmonary: Tachypnea, wheezing, bilateral crackles.

Renal/hepatic: Negative.

Endocrine: Negative.

Heme/coag: Hgb 50 g/L, Hct 0.228.

Current Medications and Allergies

Medications: none

Allergies: not known

Physical Examination

General: Acute distress.

Weight: 22 lbs (10 kg).

VS: BP 90/60, Pulse 152, RR 45, SpO2 88%, T 39.5°C.

Airway: Patent, no signs of airway obstruction. Mallampati 1, neck full range of motion.

Lungs: Tachypnea, wheezing, bilateral crackles.

Heart: Tachycardia, regular rhythm, systolic murmur 3/6.

Laboratory, Radiology, and Other Relevant Studies

CBC: WBC 15.4 X 10^9/L, neutrophils 74%, lymphocytes 22%, Hb 50 g/L, Hct 0.228

Chest x-ray: lobar consolidation involving the right upper and middle lobes.

Malaria quick test: Negative

SUMMARY AND COMMENTS FROM PREVIOUS SIMULATIONS

We presented this simulation scenario at our simulation centre SIMNOVA, University of Piemonte Orientale, Novara, Italy during a dedicated training program ("Humanitarian Medic" www.humanitarianmedic.org) aiming at training medical staff to operate in low-resources environments and humanitarian missions, such as in the case of Doctors without Borders missions. To our experience, the scenario can be easily tailored to participants of different specialties and training levels. In previous courses we exposed this scenario to Pediatricians, Anesthetists and Emergency Physicians. All three professional figures were able to manage the scenario using a problem-oriented approach, however only paediatricians or professionals that have already operated in low-resources endemic areas were more prone to reach the final diagnosis of acute chest syndrome.

Regarding crisis resource management and teamwork this scenario offers great opportunity to stress some organizational and ethical aspects very common in such situations and at which medical staff should think about when working in a resource-constrained setting. One of the aspects that we wanted to stress with this scenario is the fact that economic and social factors are some of the most common barriers influencing health decisions in low and middle-income

countries[10]. New field operators to these settings might end up pushing for specific medical care (i.e. propose a very expensive and long ambulance transfer to the main hospital) when this might not be economically or socially feasible for the family or the patient. The overall idea for this scenario is not only to train about a very common medical condition in sub-saharan africa but also to introduce and allow participant to reflect on topics such as cultural sensitivity. This opens up a great point for discussion during the debriefing. Other topics for debriefing include the differential diagnosis of paediatric respiratory insufficiency, diagnosis and treatment of acute chest syndrome and management of airways and anaemia[10]. Moreover, communication management between the local family and the national staff, cultural sensitivity and appropriateness of care based on the context.

SESAM
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Assessment of newborn resuscitation skills: a pilot study among paediatric residents using high fidelity simulation

Format: Accepted for Oral Presentation
Subject: Patient Safety / Quality Improvement

Authors

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Introduction & Aims

A prompt beginning of an appropriate neonatal resuscitation is critical to reduce mortality and improve outcome in newborns. However, residents are rarely exposed to real emergency situations. Simulation-based training offers the opportunity to improve medical skills in a controlled setting. Aim of this study was to evaluate technical (TS) and non-technical (NTS) skills in a sample of Italian paediatric residents using a standard scenario and validated checklists.

Methods

35 Italian paediatric residents attended a simulation-based training developed by SIMNOVA (Novara) and SimMeyer (Florence) called “Paediatric Simulation Experience”. The high fidelity scenario consisted of a term newborn with severe asphyxia and pneumothorax. The recorded scenarios were revised by two blinded investigators; TS and NTS were scored using validated scales.

Results & Discussion

In our sample the scores for TS and NTS were 11.8±2.2 and 3.5±1.1, respectively. The mean adherence to 2015 ILCOR guidelines for each item was 59.1±34.2%. However, a compliance below the 30% was observed in several TS items: “checks chest movements” 14.3%, “provides oxygen according to saturation” 28.6%, “increases oxygen concentration to 100% during chest compressions” 0% and “asks to start chest compressions at proper time” 14.3%. A strong correlation between TS and NTS was observed: overall performance ($r=0.71$, $p<0.05$), situational awareness skills ($r=0.86$, $p<0.05$), resource utilisation skills ($r=0.85$, $p<0.05$) and communication skills ($r=0.79$, $p<0.05$). Our study highlights the importance of both TS and NTS for a successful neonatal resuscitation. We believe that high fidelity simulation provides a useful tool during medical training of young paediatric residents.

HEART RATE ASSESSMENT USING NeoTap Advanced Support : A SIMULATION STUDY.

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ABSTRACT

Background: NeoTapAdvancedSupport (NeoTapAS) is a mobile application, based on a screen tapping method that calculates the heart rate (HR). We aimed to evaluate the accuracy of NeoTapAS in reliably determining HR from auscultation in a high-fidelity simulated newborn resuscitation scenario.

Methods: Pediatric residents assessed HR by auscultation plus NeoTapAS in an asphyxiated term infant scenario and orally communicated the estimated HR. An external observer simultaneously documented the actual HR set in the manikin and the communicated HR.

Results: One hundred sixty HR measurements were recorded. The agreement between communicated and set HR was good (Cohen's kappa 0.80, 95% CI 0.72 to 0.87; Bangdiwala's weighted agreement strength statistic 0.93). Bland-Altman plot showed a mean difference between communicated and set HR values of 1 bpm (95% agreement limits -9 to 11 bpm).

Conclusion: NeoTapAS showed a good accuracy in estimating HR and it could be an important tool in resource-constrained settings.

INTRODUCTION

Heart rate (HR) is the most important clinical parameter to evaluate newborn status. HR is also an indicator of the adequacy of resuscitative efforts and drives medical decisions.[1]

Guidelines on neonatal resuscitation recommend assessing the HR by auscultation along the left side of the chest and by counting the number of beats in 6 seconds and multiplying by 10.

Previous studies have shown that clinical HR determination can be inaccurate due to imprecise auscultation and/or errors in mental computation.[2,3] HR can also be provided by pulse oximetry and electrocardiogram (ECG) monitor.[1] However, pulse oximetry is affected by motion artifacts and delay in HR display, and availability of ECG is limited in delivery rooms, especially in low-resource settings.

Incorrect HR determination may lead to inappropriate or delayed treatment, and to fail resuscitation.[1] Using a calculator may reduce mental computation errors and increase the accuracy of HR determination. NeoTapAdvancedSupport (NeoTapAS) is a mobile application based on a screen tapping method and calculates the HR after a minimum of three taps, allowing a fast recording of HR (www.tap4life.org).

The aim of this study was to evaluate the accuracy of NeoTapAS in reliably determining HR from auscultation in a high-fidelity simulated newborn resuscitation scenario.

METHODS

This is a simulation study perfomed at the SIMNOVA Center of the University of Piemonte Orientale in Novara (Italy). The Ethics Committee of “Maggiore della Carità” Hospital (Novara, Italy) deemed that a formal ethical approval was not required since the study used manikin data. Participants gave their consent to record the scenario and to use the data.

The primary outcome was the agreement between set HR and communicated HR. The secondary outcome was participants’ satisfaction on the simulation and the app. Satisfaction was assessed using a 5-item questionnaire. Each item was a Likert scale ranging from 1 (strong disagree) to 5 (strong agree).

The scenario consisted of an asphyxiated term infant needing a complex resuscitation including positive pressure ventilation, endotracheal intubation, chest compressions, and emergency medications (neonatal simulator manikin: Newborn HAL S3010; Gaumard Scientific, Miami, Florida). HR, respiratory rate, and breath sounds were controlled remotely and could be assessed by auscultation of the thorax and observation of chest movements. Oxygen saturation via pulse oximetry (SpO2) was displayed on the bedside monitor about 40 seconds after the positioning of the oximeter probe whereas HR was not available. The SpO2 was not shown on the monitor when HR<60 beats per minute (bpm). The external observer provided verbal feedbacks during the scenario only if specifically required by the team and not provided by the manikin (i.e. the presence of secretions). A bedside Apgar timer was available for the team.

All pediatric residents from third to fifth year of residency of the University of Piemonte Orientale who were trained on neonatal resuscitation participated in the study. They were divided into teams including 3 residents (one from each year of residency, in order to balance team experience) and were asked to assume the roles of team leader and assistants. After a short training on NeoTapAS and familiarization with the manikin, participants were involved in the scenario. During each simulation, the participant responsible for HR assessment estimated the HR by listening to the praecordium with a stethoscope and simultaneously tapping the same pace on the screen of an iPad with the NeoTapAS app installed. As soon as he/she was sure of the HR displayed on the screen, he/she verbally communicated it to the team. An external observer simultaneously documented the actual HR set in the manikin and the communicated HR. All scenarios were video-recorded, stored, and reviewed by the same observer to confirm the data collected during the simulation.

NeoTapAS is a free-of-charge mobile application based on a screen tapping method (www.tap4life.org) and calculates the HR after a minimum of three taps (Supplementary Video).

Statistical analysis was performed using R 3.3 (R Foundation for Statistical Computing, Vienna, Austria). Assuming an expected Cohen's kappa of 0.80, at least 145 measurements were required to provide a 2-sided 95% confidence interval with width of 0.20. We finally performed 160

measurements to ensure the same number of role as HR assessor among the 40 participants. Agreement between set HR and communicated HR was evaluated using weighted Cohen's kappa, Bangdiwala's agreement chart and Bland-Altman plot. All tests were 2-sided and a p-value less than 0.05 was considered statistically significant.

RESULTS

Forty residents participated in the study and 160 HR measurements were recorded. Data on HR categories as set in the manikin and as communicated by participants are shown in Table 1. The agreement between communicated HR and set HR categories was good (Cohen's kappa 0.80, 95% CI 0.72 to 0.87). Bangdiwala's weighted agreement strength statistic was 0.93 (Figure 1). Bland-Altman plot (Supplementary Figure 1) indicated a mean difference between communicated HR and set HR values of 1 bpm (95% agreement limits -9 to 11 bpm). All participants answered the questionnaire on satisfaction and agreed that NeoTapAS improved HR evaluation, while its effects on promptness of resuscitation and on decision-making were less strong (Supplementary Figure 2).

DISCUSSION

NeoTapAS showed good accuracy in estimating HR although it led to partial overestimation when HR was below 60 bpm.

International guidelines on neonatal resuscitation recommend HR determination by physical examination, but this approach may lead to inaccurate HR estimation in 33%-75% of cases,[2,3] potentially compromising resuscitation interventions. It is unknown whether inaccuracy is due to imprecise auscultation, wrong mental computation or combination of both. Hawkes et al. reported low accuracy of tapping HR on the resuscitation table during HR auscultation.[4]

NeoTapAS avoids mental computation, thus potentially increasing accuracy in HR assessment. Our results indicated good accuracy of NeoTapAS, in agreement with a previous study.[5] NeoTapAS limited the overestimation to 31% of cases with HR<60 bpm, while a recent simulation study reported an overestimation of 69%-83%.[4] In addition, NeoTapAS was inaccurate in 6% of cases with HR between 60-100 bpm, and 11% in cases with HR over 100 bpm.

ECG monitor during neonatal resuscitation would provide fast and accurate HR assessment,[1] but its availability is limited, especially in low-resource settings. Moreover, the use of ECG at birth may delay signal acquisition due to skin cleaning, leads placement, potential skin damage in extremely low birth weight infants and incorrect interpretation of a pulseless electric activity. Despite these limitations, ECG remains the gold standard and NeoTapAS will need to be compared to ECG in real life scenarios.

Participants believed that NeoTapAS was useful in improving HR evaluation, while its effects on promptness of resuscitation and on decision-making were less strong. We observed no problems with the participants tapping on the screen and HR communication was very fast (median 6 seconds). With respect to mental calculation, NeoTapAS avoids mental computation and directly provides HR calculation, thus it can become a useful tool for health care staff in such stressful situation. It should be noted that our findings may be different in real-life situation. Moreover, participants were pediatric residents with limited experience in neonatal resuscitation.

In conclusion, NeoTapAS showed good accuracy in estimating HR, despite partial overestimation when HR<60 bpm. This free-of-charge mobile application could be an important resource in settings with limited availability of ECG.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Heart rate is the most important clinical indicator to evaluate the status of a newborn and to drive neonatal resuscitation.

Previous studies have shown that HR determination by auscultation can be inaccurate leading to inappropriate or delayed treatment.

WHAT THIS STUDY ADDS

NeoTapAdvancedSupport is a mobile application that provides an accurate estimation of HR in a simulated scenario of neonatal resuscitation.

NeoTapAdvancedSupport could be a useful tool in resource-constrained settings and where an electrocardiogram monitor is not promptly available.

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TABLES

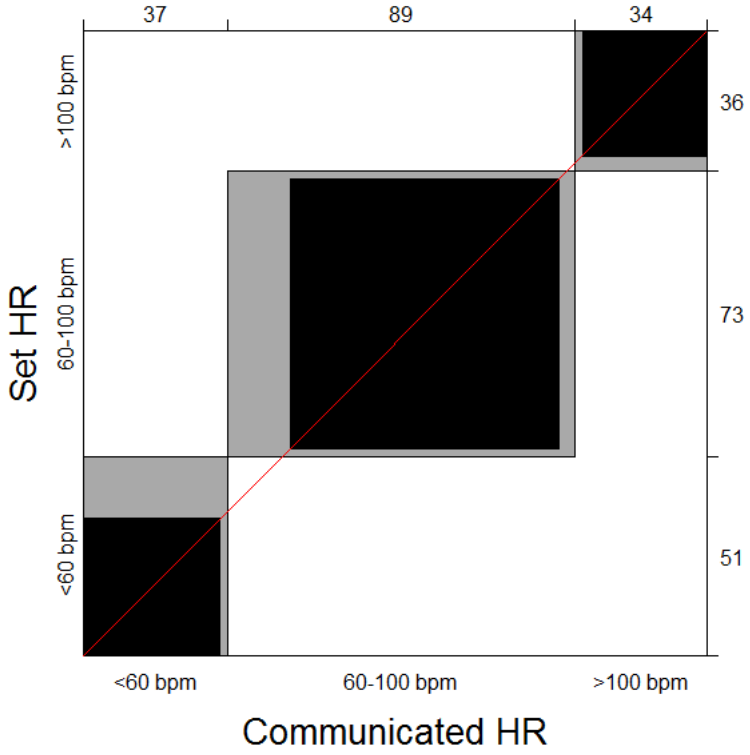
Table 1. Distribution of HR as set in the manikin and as communicated by participants.

	Communicated HR			
Set HR	<60 bpm	60-100 bpm	>100 bpm	Total
<60 bpm	35 (69%)	16 (31%)	0 (0%)	51
60-100 bpm	2 (3%)	69 (94%)	2 (3%)	73
>100 bpm	0 (0%)	4 (11%)	32 (89%)	36

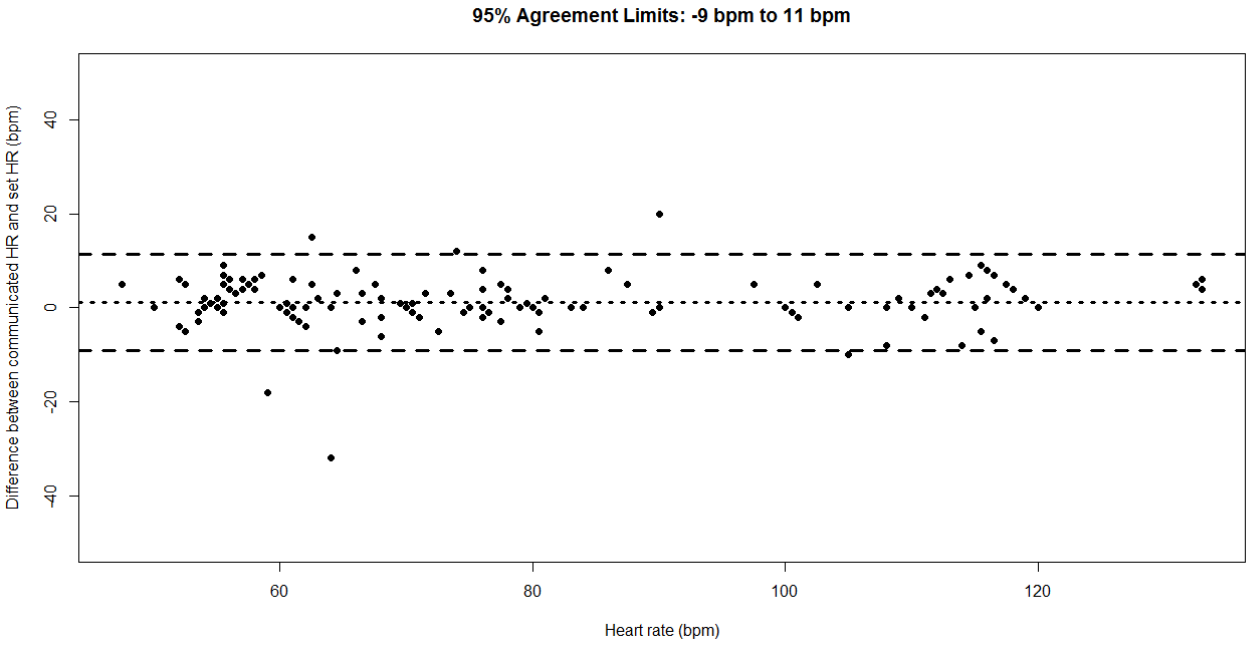
Total	37	89	34	160

No. (%) of measurements.

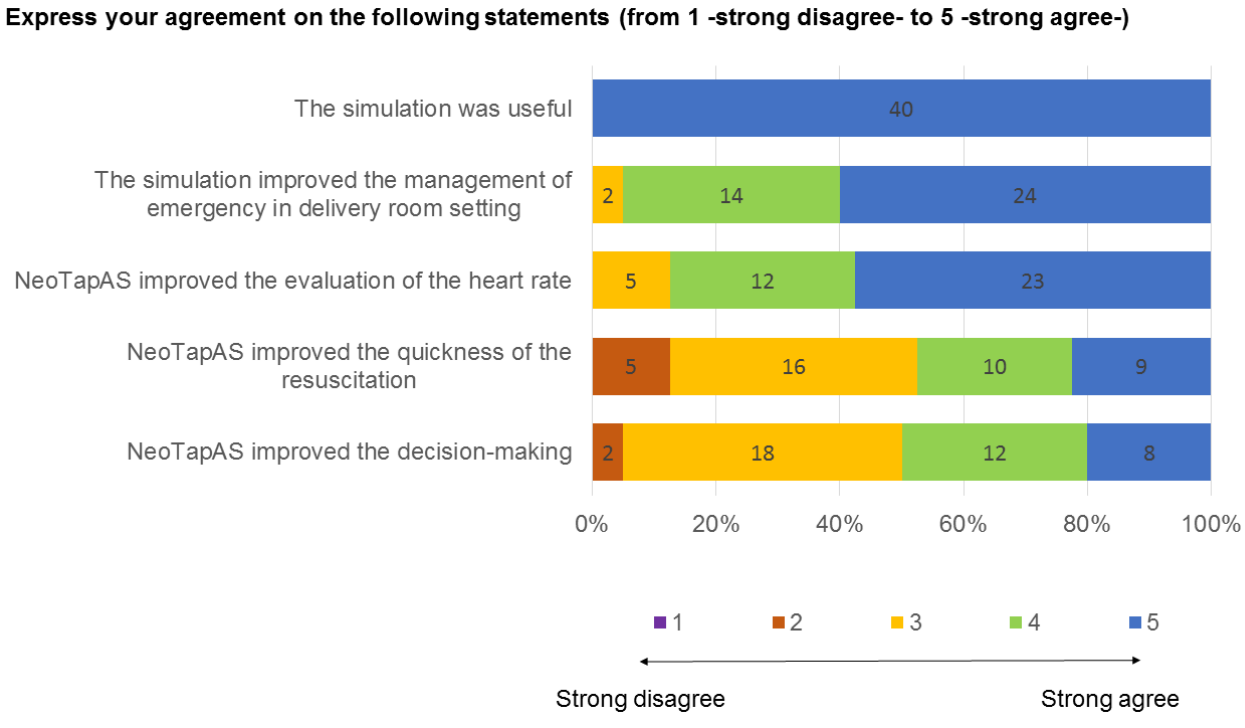
Figure 1. Bangdiwala's agreement chart between set HR and communicated HR categories (Bangdiwala's weighted agreement strength statistic: 0.93). Observed and expected diagonal elements of the confusion matrix are represented by superposed black and white rectangles. Partial agreement is represented by grey rectangles.



Supplementary Figure 1. Bland-Altman plot for HR assessment.



Supplementary Figure 2. Satisfaction about the simulation and the app. Each item is a Likert scale ranging from 1 (strong disagree) to 5 (strong agree).



Impact of a mobile application for heart rate assessment in simulated neonatal resuscitation: a randomized controlled crossover study.

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ABSTRACT

Background: Clinical assessment of newborn heart rate (HR) at birth has been reported to be inaccurate. NeoTapAdvancedSupport (NeoTapAS) is a free-of-charge mobile application that showed good accuracy in HR estimation. This study aimed to evaluate the impact of NeoTapAS on timing of HR communication and of resuscitation interventions.

Methods: This was a randomized controlled crossover (AB/BA) study evaluating HR assessment using auscultation plus NeoTapAS compared with auscultation plus mental computation in a high-fidelity simulated newborn resuscitation scenario. Twenty teams each including 3 pediatric residents were randomly assigned to AB or BA arms. The primary outcome was the timing of the first HR communication. Secondary outcomes included the timing of the following four HR communications and the timing of resuscitation interventions (positive pressure ventilation, chest compressions, intubation and administration of first dose of adrenaline).

Results: NeoTapAS reduced the time to the first HR communication (mean difference -13 seconds, 95% CI -23 to -4; p=0.009), and anticipated chest compressions (mean difference -68 seconds, 95% CI -116 to -18; p=0.01) and administration of adrenaline (mean difference -76 seconds, 95% CI -115 to -37; p=0.0004) compared with mental computation.

Conclusions: In a neonatal resuscitation simulated scenario, NeoTapAS reduced the time to the first HR communication and anticipated chest compressions and administration of adrenaline compared with mental computation. This app can be especially useful in settings with limited availability of monitoring equipment, but further studies in clinical scenarios are warranted.

INTRODUCTION

Heart rate (HR) is the most important clinical indicator to evaluate the status of a newborn and to guide neonatal resuscitation (1,2). Furthermore, HR during the first minutes of life could be a predictor of early neonatal mortality and morbidity (3). International guidelines on neonatal resuscitation recommend assessing the HR by auscultation along the left side of the chest and by counting the number of beats in 6 seconds and multiplying by 10 (1,2). Pulse oximetry and 3-lead electrocardiogram (ECG) monitor can also be used to assess HR in delivery room (1), but some limitations (i.e. motion artifacts and delay in HR display when using pulse oximetry, and availability of 3-lead ECG in delivery rooms) hamper their use especially in low-resource settings.

Assessing the HR by auscultation can be limited due to imprecise auscultation and/or errors in mental computation (4,5), leading to inappropriate or delayed resuscitation (1). Previous studies evaluated a free-of-charge mobile application (NeoTapAdvancedSupport, NeoTapAS) (6) to help HR assessment in a simulated scenario of neonatal resuscitation (7,8). NeoTapAS showed good accuracy in estimating HR and could be a useful tool in resource-constrained settings (8).

Another potential advantage of using NeoTapAS may be the anticipation of HR communication during resuscitation, because it avoids mental computation and possible errors due to the stressful

situation. (9) In addition, prompt HR assessment may lead to anticipating resuscitation interventions. However, these hypotheses remain to be demonstrated.

The aim of this study was to evaluate the promptness in HR communication using NeoTapAS compared with mental computation in a high-fidelity simulated newborn resuscitation scenario. In addition, the impact of NeoTapAS on timing of resuscitation procedures was investigated.

METHODS

Study design

This was a randomized controlled crossover (AB/BA) study evaluating the promptness in HR communication using auscultation plus NeoTapAS compared with auscultation plus mental computation in a high-fidelity simulated newborn resuscitation scenario The AB/BA scheme is uniform within sequences and periods, thus removing any period and sequence effects (10). The Ethics Committee of “Maggiore della Carità” Hospital (Novara, Italy) deemed that a formal ethical approval was not required since the study used manikin data. Participants gave their consent to record the scenario and to use the data.

Setting

This simulation study was performed at the SIMNOVA Center of the University of Piemonte Orientale in Novara (Italy). The scenario consisted of an asphyxiated term infant needing a complex resuscitation including positive pressure ventilation, endotracheal intubation, chest compressions, and emergency medications (neonatal simulator manikin: Newborn HAL S3010; Gaumard Scientific, Miami, Florida), as described elsewhere (8). Briefly, HR, respiratory rate, and breath sounds were controlled remotely and could be assessed by auscultation of the thorax and observation of chest movements. Oxygen saturation via pulse oximetry (SpO2) was displayed on the bedside monitor about 40 seconds after the positioning of the oximeter probe whereas HR was not available. The external observer provided verbal feedbacks during the scenario only if

specifically required by the resuscitation team and not provided by the manikin (i.e. the presence of secretions). A bedside Apgar timer was available for the resuscitation team.

Randomization

All pediatric residents from third to fifth year of residency of the University of Piemonte Orientale who were trained on neonatal resuscitation participated in the simulation. They were divided into teams including 3 residents (one from each year of residency, in order to balance team experience) and were asked to assume the roles of team leader and assistants. After a short training on NeoTapAS and familiarization with the manikin, residents were involved in the scenario. Teams were randomly assigned to AB or BA arms in a 1:1 ratio. Randomization was performed using a computer-generated random assignment list. Arm assignments were included in sealed opaque envelopes sequentially numbered.

Procedures

Teams in AB arm were assigned to HR assessment by auscultation and tapping on NeoTapAS, followed by HR assessment by auscultation and mental computation. Participants in BA arm were assigned to the reverse sequence. A washout period of one day was included to reduce any carryover effect.

During each simulation, the resident responsible for HR assessment estimated the HR by listening to the praecordium with a stethoscope. When using NeoTapAS, he/she simultaneously tapped the same pace on the screen of an iPad with the NeoTapAS app installed (8) and verbally communicated the HR displayed on the screen. When using mental computation, he/she mentally calculated the HR based on auscultation (by counting the number of beats in 6 seconds and multiplying by 10) and verbally communicated the calculated HR.

All resuscitations were performed according to the Neonatal Resuscitation Program (NRP) 7th edition algorithm, including the timing of HR assessment (11). All scenarios were video-recorded, stored, and reviewed by the same observer to confirm the data collected during the simulation.

NeoTapAS is a free-of-charge mobile application specifically designed for registration of neonatal resuscitation events (6). It is based on a screen tapping method and calculates the HR after a minimum of three taps, allowing a fast recording of HR and a real-time event registration (8).

Outcomes

The primary outcome was the timing of the first HR communication. The secondary outcomes included the timing of the following (second, third, fourth, fifth) HR communications and the timing of resuscitation interventions (positive pressure ventilation, chest compressions, intubation and administration of first dose of adrenaline).

Sample size

Assuming a true mean difference of 10 seconds (SD 15) in the primary outcome between the two methods, with type I error of 0.05 and a power of 0.80, 20 teams (10 in AB arm and 10 in BA arm) are required to be enrolled in the study.

Statistical analysis

Continuous data were expressed as mean and standard deviation (SD), and categorical data as number and percentage.

The study included a washout period that was chosen to reasonably prevent carryover effects. Since tests for carryover effect are generally underpowered, an adequate washout period is strongly recommended to prevent carryover effects (12). Primary and secondary outcomes were compared using the 2-sample t test approach on paired data (13). Period effects were also tested for using the 2-sample t test approach on paired data (13). All test were 2-sided and a p-value less than 0.05 was considered statistically significant. Statistical analysis was performed using R 3.3.0 (R Foundation for Statistical Computing, Vienna, Austria) (14).

RESULTS

Primary outcome

Timing of first HR communication is shown in Table 1. Time to the first HR communication was shorter with NeoTapAS compared with mental computation (mean difference -13 seconds, 95% CI -23 to -4; p=0.009). No period effect was found (p=0.38).

Secondary outcomes

Timing of second to fifth HR communications is shown in Table 1. Time intervals to the second (mean difference -16 seconds, 95% CI -33 to 1; p=0.07) and to the third (mean difference -24 seconds, 95% CI -48 to 1; p=0.06) HR communications were slightly shorter with NeoTapAS compared with mental computation. No period effect was found (p=0.76 and p=0.77, respectively). NeoTapAS and mental computation had similar time intervals to the forth and to the fifth HR communications (p=0.81 and p=0.53, respectively; Table 1). No period effect was found (p=0.57 and p=0.85, respectively).

Timing of resuscitation interventions is shown in Table 2 and Figure 1. Start of positive pressure ventilation was similar with NeoTapAS and mental computation (mean difference -6 seconds, 95% CI -15 to 3; p=0.20). No period effect was found (p=0.93). Chest compressions started earlier with NeoTapAS compared with mental computation (mean difference -68 seconds, 95% CI -116 to -18; p=0.01). No period effect was found (p=0.30). Timing of intubation was similar with NeoTapAS and mental computation (mean difference -29 seconds, 95% CI -87 to 30; p=0.29). No period effect was found (p=0.10). First dose of adrenaline was administered earlier with NeoTapAS compared with mental computation (mean difference -76 seconds, 95% CI -115 to -37; p=0.0004). The period effect was close to statistical significance (p=0.07).

DISCUSSION

In a neonatal resuscitation simulated scenario, NeoTapAS reduced the time to the first HR communication compared with mental computation. In addition, NeoTapAS anticipated chest compressions and administration of adrenaline compared with mental computation.

Heart rate (HR) is the most important clinical indicator to guide appropriate interventions during neonatal resuscitation (1,2). HR evaluation by auscultation is currently recommended, but imprecise auscultation and/or errors in mental computation can reduce the precision of this approach (4,5). This limit can be overcome by the introduction of an instrumental aid. NeoTapAS is a free-of-charge mobile application (6) that proved good accuracy in estimating HR in manikin studies (7,8). This application can be especially useful in settings where monitoring equipment (i.e. pulse oximetry and 3-lead ECG) is lacking.

Beyond good accuracy, using this application may allow to anticipate HR communication during neonatal resuscitation. Our study showed that NeoTapAS reduced the time to the first HR communication of a mean of 16 seconds compared with mental computation. Furthermore, NeoTapAS seemed promising in reducing the second and third HR communications, but these outcomes needed to be addressed in further studies.

The scope of shortening the times to HR communication is to anticipate the initiation of resuscitation interventions. Our results indicated that NeoTapAS anticipated the start of chest compressions (by a mean of 68 seconds) and the administration of the first dose of adrenaline (by a mean of 76 seconds) compared with mental computation. The magnitude of these anticipations may be clinically relevant in neonates needing advanced resuscitation, because the timing of cardiovascular support plays a crucial role in neonatal resuscitation (1,2).

Surprisingly, NeoTapAS was not associated with early initiation of positive pressure ventilation, despite the anticipated first HR communication. In our study, we observed that positive pressure ventilation was performed before first HR communication in 7 out of 10 procedures, thus suggesting

a decision based on observed apnea. In fact, international guidelines recommend initiating positive pressure ventilation in case of apnea and/or gasping and/or HR below 100 bpm (1,2).

This is the first study evaluating the impact of a mobile application for heart rate assessment (NeoTapAS) on the times of HR communication and of resuscitation procedures in a high-fidelity simulated newborn resuscitation scenario. A recent study suggested that a quick and reasonably accurate HR assessment could be achieved by auscultation in low-risk newborns (i.e. those not anticipated to need resuscitation and those with HR>100 bpm), but no conclusions could be made for infants needing resuscitation or in the setting of bradycardia (15). According to our findings and to the good accuracy reported in a simulated scenario of neonatal asphyxia (8), NeoTapAS can be a promising instrument for neonatal resuscitation, but further studies should evaluate its impact on real-life situation and on neonatal outcomes.

This study has some limitations that should be considered when reading the results. First, findings from a simulation study might be different in a real-life situation where other clinical signs are available. Second, participants were pediatric residents with limited experience in neonatal resuscitation, while more experienced health care providers (i.e. Neonatal Intensive Care Unit staff) may achieve different results.

CONCLUSIONS

In a neonatal resuscitation simulated scenario, NeoTapAS reduced the time to the first HR communication and anticipated chest compressions and administration of adrenaline compared with mental computation. This app can be especially useful in settings with limited availability of monitoring equipment. Further studies are needed to evaluate the impact of this app in real-life situation and on neonatal outcomes.

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DISCUSSION

Healthcare simulations can be said to have four main purposes: education, assesment, health system integration in facilitating patient safety and research. As simulation is increasingly used to study questions pertaining to pediatrics, it is important that investigators use rigorous methods to conduct their research. From a pediatric perspective, the 2 main types of simulation-based research are: studies that assess the efficacy of simulation as a training methodology and studies where simulation is used as an investigative methodology. Research using simulation as an investigative methodology make use of the standardization provided by simulation to answer diverse research questions that otherwise could not be answered feasibly, safely, ethically, or in a timely fashion in clinical settings.

Overall aim of the present project is to inquire the use of simulation as investigative methodology in pediatric and neonatal settings. The simulated environment is used as an experimental model to

study factors affecting human and systems performance and to evaluate the effect of new technology on clinical performance.

Previously, we conducted a survey among Italian pediatric residents on the use of simulation for training and research: respondents were associated with 71% of the Italian universities with a pediatric specialisation programme. This survey reveals the scarce use of SBMT by Italian paediatric residency programmes and points out the main barriers that prevent SBMT diffusion. This is a call to action to develop organised SBMT during paediatric residency programmes, to train qualified personnel and to carry out research in this field in order to improve the quality of education and care.

As second step we evaluated newborn resuscitation skills in a sample of 35 Italian pediatric residents. The mean adherence to 2015 ILCOR guidelines for each item was 59.1±34.2%. However, a compliance below the 30% was observed in several Technical S items: “checks chest movements” 14.3%, “provides oxygen according to saturation” 28.6%, “increases oxygen concentration to 100% during chest compressions” 0% and “asks to start chest compressions at proper time” 14.3%. A strong correlation between TS and NTS was observed: overall performance ($r=0.71$, $p<0.05$), situational awareness skills ($r=0.86$, $p<0.05$), resource utilization skills ($r=0.85$, $p<0.05$) and communication skills ($r=0.79$, $p<0.05$). Our study highlights the importance of both TS and NTS for a successful neonatal resuscitation. We believe that high fidelity simulation provides a useful tool during medical training of young paediatric residents. Following this research, we have developed scenarios for training, in order to spread the culture of learning without risk for the patient. Effective simulation is not dependent on the purchase and use of highly complex and expensive patient simulators; more important are carefully designed scenarios that align with the needs of the learners, provision of important (not necessarily all) cues, and conduct of skillfully led debriefings

Finally, we designed a simulation-based study to investigate the effect of a new technology called “Neotap” on neonatal resuscitation performance. NeoTap is a free-of-charge IOS health application based on a screen tapping method, allowing fast calculation of HR after a minimum of three taps.

With respect to mental calculation, NeoTapAS avoids mental computation and directly provides HR calculation, thus it can become a useful tool for health care staff in such stressful situation. In a neonatal resuscitation simulated scenario, NeoTapAS reduced the time to the first HR communication compared with mental computation. In addition, NeoTapAS anticipated chest compressions and administration of adrenaline compared with mental computation. It should be noted that our findings may be different in real-life situation. Moreover, participants were pediatric residents with limited experience in neonatal resuscitation. In conclusion, NeoTapAS could be an important resource in settings with limited availability of ECG.

CONCLUSIONS AND FUTURE PERSPECTIVES

The current use of simulation in health care barely taps its full potential. Despite the low diffusion of simulation-based learning (SBL) in Italy, paediatric residents show an extremely high interest in acquiring basic knowledge of SBL. They perceive its potential key benefits to improve decision-making abilities in complex medical situations and to learn technical/procedural and non-technical skills.

Simulation is an extremely useful, but rarely employed, research strategy. It should be considered whenever faced with clinical investigations that are difficult to conduct in the real health care environment.

We designed a new simulation-based multi-center research project (*Simarrest*) in collaboration with University of Padua, in order to:

1. identify gaps about in-hospital pediatric cardiac arrest management in a simulation setting;
2. evaluate the compliance with the principles of the CRM;
3. evaluate the satisfaction of the study participants with respect to the management of the presented scenario.

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