

***TITLE: MANIKIN TO PATIENT INTUBATION: DOES IT TRANSLATE?"***

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**Study Title:** *“Manikin To Patient Intubation: Does It Translate?”*

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## **Abstract**

Tracheal intubation of infants and children is a critical lifesaving skill, and its importance is recognized by the Accreditation Council on Graduate Medical Education (ACGME), Residency Review Committee (RRC), the Neonatal Resuscitation Program (NRP) and Pediatric Advanced Life Support (PALS) programs. Despite its importance, current training is lacking in teaching this critical procedural skill as demonstrated by the inability of up to 1/3 of upper level Pediatric residents to be able to successfully intubate Very Low Birth Weight (VLBW, <1500 grams) neonates. New technology, which has now been adapted to the existing telemedicine network in Arkansas, offers an exciting opportunity to improve the ability of pediatric trainees to accomplish this critical task. We will utilize a deliberate practice approach with immediate feedback during neonatology rotations using the Storz video laryngoscope to teach this critical skill to Pediatric and Med-Peds residents (n=95 residents total). Previous work demonstrated improvement in skills with a manikin, but it is unknown if these skills will translate to live intubations. The residents will receive training during alternating months, and will be recorded during live intubations. We will assess how intubation skills using a manikin translates to live patients. We anticipate this training will dramatically improve intubation skills and resident confidence as evidenced by intubation accuracy.

## **Project Narrative**

### **Background and Significance**

Tracheal intubation is one of the most important interventions in the stabilization of critically ill or injured children. Advanced airway skills training is one of the major pillars of the ACGME pediatric program requirements for resident and fellowship education (Accreditation Council for Graduate Medical Education, 2007). The pediatric airway presents unique anatomic challenges depending on the patient age, size and underlying condition. These challenges, coupled with low frequency of pediatric trainee exposure to advanced airway management, make tracheal intubation procedural competency difficult to achieve. As a result, tracheal intubation in infants and children is associated with high levels of operator stress as well as patient morbidity and mortality.<sup>1-3</sup>

The ability to manage the pediatric airway, which includes anticipating potential difficulties and choosing an appropriate approach, remains one of the most vital skills to develop when caring for critically ill children. Provider training level has been found to correlate with patient outcome during advanced airway management in selected environments including the operating room, delivery room and Neonatal Intensive Care Unit (NICU).<sup>3-5</sup> Pediatric trauma patients intubated by less experienced emergency medical personnel in the field have increased morbidity and mortality when compared to similar patients intubated by pediatric-trained hospital personnel.<sup>6</sup> A limited number of studies from neonatal resuscitation demonstrated that resident trainee success rates are moderate at best, with 1/3 of upper level pediatric residents unable to intubate a very low birth weight (<1500 grams) neonate.<sup>5,7,8</sup> The RRC agreed that neonatal intubation is a critical skill, but respondents to a survey sent to Residency Program Directors determined that "many residents do not develop competence in that area" and that a "more robust and standardized method is needed for teaching procedural skills and for documenting

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competence".<sup>9</sup> A survey of pediatric emergency room directors found that the number of intubations necessary to maintain skill in this area was inadequate.<sup>10</sup> Even more concerning is that procedural skills such as intubation deteriorate rapidly over time (within the first year).<sup>11</sup>

Our findings suggest that the training of pediatric residents is not sufficient prior to "live" tracheal intubations in the critical care setting. The current one to two days of airway management training as a part of resuscitation training (such as PALS or NRP) is not sufficient to provide safe intubation skills. A new approach to the instruction of tracheal intubation is needed for pediatric trainees, to decrease adverse events and to improve patient safety.<sup>12</sup> One approach would be to develop and implement tracheal intubation training using concepts of deliberate practice modeled after Ericsson. The concepts include focused training on a specific task, immediate feedback, time for problem solving and evaluation, and opportunities for repeated performance.<sup>13,14</sup> All pediatric residents will be required to meet a pre-set training goal (intubating a manikin consistently within 15 seconds, half the time allowed by NRP) in a simulation setting with intense, repeated training with feedback. This proposal is an attempt to develop such a training model.

Video laryngoscopy offers a potential solution to the problem of intubation training, because it allows the educator to actually "see" what the trainee is seeing with the laryngoscope. Although this mode of intubation has been used for some time with adult laryngoscopy, the technology has only recently been adapted for neonatal and pediatric use. One recent study found satisfaction with the proposed equipment, but patients were not randomized and its use in training has not been studied.<sup>15</sup> The GlideScope, another brand of video laryngoscopy, has been used in children, providing better views, but intubation takes longer using this technology,<sup>16,17</sup> and it does not adapt well for use in neonates and infants because of blade size. Interestingly, Skype has been used with this technology, but Skype offers limited resolution and is not HIPAA compliant.<sup>18</sup> *We have been able to demonstrate that this equipment significantly decreases intubation times in manikins. Now we must determine if this improvement translates into improved intubation skill in live patients.*

### **Hypothesis and/or Specific Aims or Objectives**

Specific Aim 1. *Assess the impact of this educational manikin intervention on live patients.*

We hypothesize learners in the Intervention Group vs. the Control Group will have enhanced success in intubation as determined by the number of attempts and time required for intubation of live patients.

Specific Aim 2. *Assess the satisfaction of this educational intervention and equipment.*

We hypothesize pediatric residents will have increased satisfaction scores and confidence for intubating live patients in the Intervention Group vs. the Control Group.

Specific Aim 3. *Assess the association of confidence in intubation with actual success in intubation.*

We hypothesize increased confidence will be associated with increased intubation success.

### **Target Audience**

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The target audience will be Pediatric and Med-Peds residents. Total n = 95 potential participants

## **Methods**

This research study will include 95 resident physicians. We anticipate 80 residents will enroll, similar to our previous study in which 82 residents participated. Residents will be randomized to the Intervention Group or the Control Group. This study will be explained to potential participants as they begin their assigned rotation to the Neonatal Intensive Care Unit (NICU). The explanation of the study and the Information Sheet will be introduced during the first five (5) days of this rotation. Residents will be allowed to ask any questions they feel necessary and take as much time as needed in order to make a fully informed voluntary consent. It will be explained that their participation in this study is completely voluntary and a decision to not participate will have no impact on their training or standing in the residency program. Randomization will occur by the month the resident is assigned to the NICU.

All participants will:

- Receive NRP training and certification offered at the beginning of their residency
- Complete a Baseline Survey
- Complete a Baseline Cognitive and Simulation Assessment
- Have a Stabilization Room video recording as part of the quality improvement process for neonatal resuscitation
- Complete a Cognitive and Simulation Assessment at the end of the month
- Complete an End of Rotation Survey

Residents who are randomized to the Intervention Group will, in addition:

- Observe a 7 minute NRP video
- Complete a hands-on intubation simulation with Dr. Hall instructing:
  - Using state of the art technology, a Storz C-MAC video laryngoscope
  - Identifying anatomical landmarks
  - Practice on the manikin until intubation occurs within 15 seconds

During the monthly rotation of each resident, ongoing data will be collected on the residents' ability to successfully intubate on the first attempt, the total number of attempts to intubate, and the total number of successful attempts at intubating a neonate within 30 seconds, the time limit set by NRP. All live intubations performed in the Stabilization Rooms will be recorded and reviewed by designated members of the NICU Safety Committee. The recorded videos of study participants will also be reviewed by Dr. Whit Hall and Jimmie Birdsong, R.N. The information obtained from the video recordings will be kept in a safe, secure file that is password protected. At the end of the monthly rotation each resident, including those in the Control Group, will be offered the opportunity to complete the Hands-on Intubation training simulation with Dr. Hall.

Angel Eye Cameras and control modules will be placed on the patient beds in the NICU Resuscitation Rooms which will be used for recording and monitoring infant intubation procedures. The cameras will be placed on the bed above the infant and staff while the control panel will be on a nearby wall to allow for easy starting and stopping of recording and monitoring of recording during the procedure. The control panel will have access to start/stop

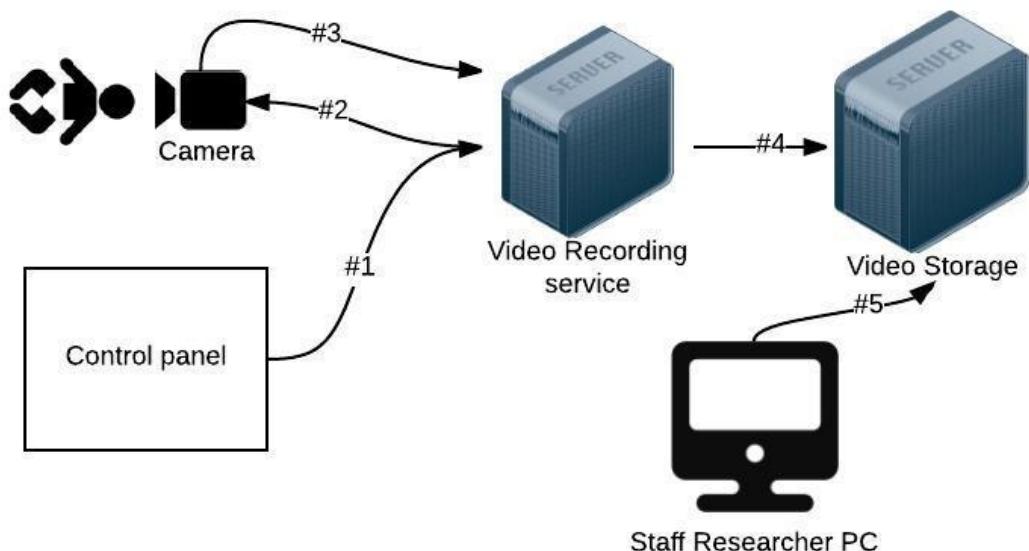
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recording as well as status and duration of recording. Recording will default to three (3) hour durations and can be extended from the control panel. All recordings will be managed by a video recording server and stored on network accessible server storage space. All videos will be labeled by date, time and bed space at which the recording took place. Staff can then log into the server and review videos to ensure proper intubation procedures have been followed and to improve training methods.

Below is a technical workflow diagram:



1. User accesses control panel to select camera at bed space. Control panel sends signal to recording server to start recording on requested camera.
2. Recording server requests video from camera.
3. Camera starts sending video and audio data to recording server.
4. Recording server stores video and audio data on video storage server.
5. Staff can then access recorded data directly from the video storage server.

## **Study Population**

### Inclusion Criteria

Male and female residents from 18-89 years of age who have been assigned to the NICU for a monthly rotation are eligible to participate. At the beginning of all NICU rotations, all pediatric residents will be invited to participate in this research.

### Exclusion Criteria

Any pediatric resident who does not wish to participate

## **Risks and Benefits**

The only potential risk to study participants is the potential for loss of confidentiality. Measures to protect the confidentiality of study participants will be implemented as described in the Data Handling and Recordkeeping section below.

There will likely be direct benefits to the study participants to include enhanced instruction in neonatal intubation which would result in enhanced procedural skills for pediatric residents. Further, knowledge gained from the study could potentially benefit residents and community providers who are required to intubate, and their patients, in the future.

## **Data Handling and Recordkeeping**

The Principal Investigator will carefully monitor study procedures to protect the safety of research subjects, the quality of the data and the integrity of the study. A unique identifying code or number will be assigned to the participant's documents. In this way the data will remain anonymous. Only R. Whit Hall, MD and Jimmie Birdsong, RN will have access to study data and this data will be kept in a locked file in the principal investigator's office. Jimmie Birdsong, RN will routinely transcribe the data collected to an electronic file using the unique identifying code or number for each participant. The electronic file will be placed on a password protected file located on the UAMS Server. All recordings will be managed by a video recording server and stored on network accessible server storage space.

## **Evaluation Plan**

Using data from our previous intubation study using a manikin, we estimate a sample size for this study is 27 residents in each group. We recruited more than that for the manikin study, and for that study residents were required to come back for a post test. Thus, we anticipate no major difficulties in recruitment.

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