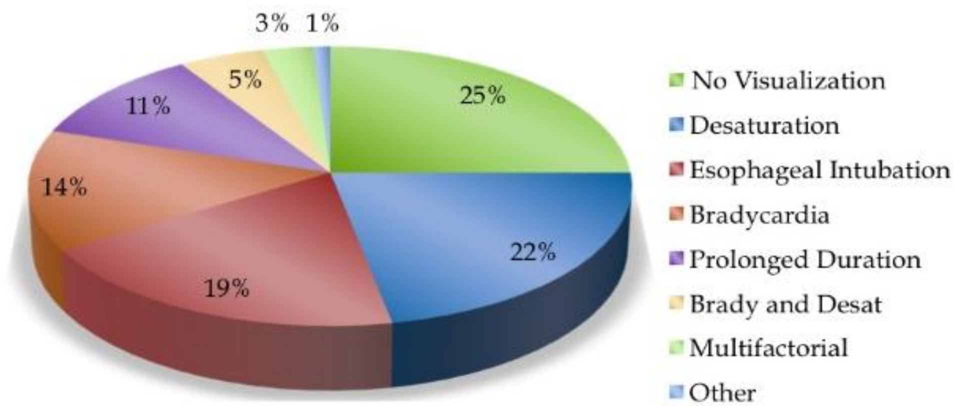
USF Health
GRADUATE MEDICAL EDUCATION

SAMPLE PROJECT PROPOSAL AND BUDGET
FOR REFERENCE ONLY

This document provides a sample project proposal and sample budget from a previous year's GME research grant program. Please note: These sample documents should be used for reference ONLY.

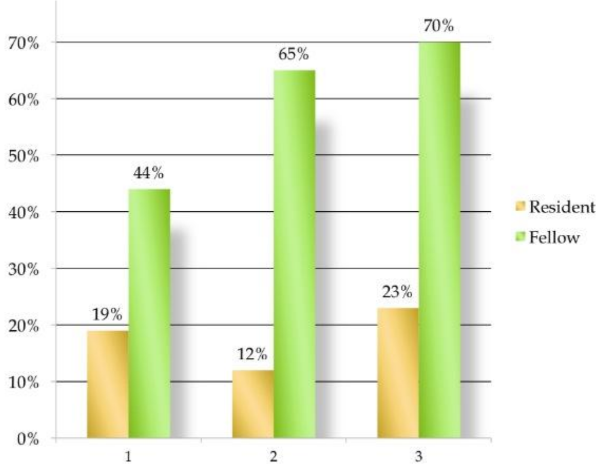
Identification of Problem and Skill Assessment in Learning Neonatal Intubation: A Descriptive Study Examining the Gaps in Procedural Proficiency

Introduction: Neonatal intubation is the most essential of all skills required by a health care professional during neonatal resuscitation. The small size of the oral cavity in neonates makes direct laryngoscopy (DL) challenging and difficult to learn and train. The difficulty in DL and tracheal intubation further increases with prematurity, increasing the failure rate and increase in the frequency of traumatic intubation. The data from a prospective observational study collected from five level III POISE Network Neonatal Intensive Care Units (NICU) has shown non-visualization of vocal cords accounting for as the cause responsible in 25% of intubation failure Fig (1). It also shows that provider factors such as inability to visualize airway, esophageal intubation, and prolonged duration accounted for the majority (55%) of failures (1)



(Figure 1) Reasons for failure (NIQI data from 5 level III NICU in POISE network A total of 458 intubations were studied)

Recent duty hour limitations and increased use of non-invasive ventilation have reduced trainee exposure to intubation. The NIQI data suggests that house staff had the lowest success rates of intubation among all health care workers and showed little improvement over the course of training (Figure 2).



(Figure 2) Poor acquisition of neonatal intubation skills in pediatric house staff: Little improvement in intubation success rate of pediatric residents (NIQI data) over 3 years of residency

Studies have shown that there are wide variation in the learning curves and the number of attempts to achieve proficiency in performing medical and surgical procedures by novices and new residents (2). Expertise literature stresses the importance of *guided* practice (3, 4) to avoid the entrenchment of bad habits or the possibility of "laboring in vain" on tasks that are too easy or too difficult to maximize the learning opportunity. (5) One of the most crucial aspects of deliberate practice is the assessment of performance by an expert accompanied by immediate feedback to allow for the correction of errors. (3, 4) Therefore it is necessary to determine the specific types of problem areas that trainees experience when learning neonatal intubation techniques and to determine the reliability with which expert teachers can identify these difficulties in trainee performance.

Supervision of the non-expert intubator/operator traditionally has been provided by the presence and verbal support of an expert provider (attending neonatologist, senior neonatal fellow or practitioner), who is trusting observations verbally relayed from the operator, rather than relying on their independent direct visual confirmation (6).
Direct laryngoscopy requires a line of sight along the blade to obtain a view to the glottis opening. The viewing angle has been measured at 15 degree and is limited by oropharyngeal structures (7). Limited space and small oral cavity obscures the view even more, especially in premature neonates, making it near impossible to assess the skill closely and identify the problem, required to train novices by deliberate practice.
A video camera at the tip of the blade can potentially provide an increased angle and a magnified view of the glottis in the normal and difficult pediatric airway. Studies in adults have shown efficacy of video laryngoscopy over DL, especially for teaching novice intubators (7). A previous pediatric study done on children less than 4 years of age has found improved glottis view compared to DL(8).

This study is designed to study the development of neonatal intubation skills by health care workers frequently involved in neonatal resuscitation in a level III NICU. The study aims to evaluate the procedure of neonatal intubation during training in the simulation lab in phase (I) and in real patients (neonates in the NICU) in phase (II) of the study.

The Storz C-MAC video laryngoscope offers size 0 and 1 Miller blades as well as display and recording capabilities via the fiberoptic camera in the light source at the tip of the blade (figure 3). The technique of placing an endotracheal tube is similar to the standard technique for direct laryngoscopy that we currently employ and teach in the NICU. As the blade is straight, the view on the screen is similar to what is seen when looking directly into the mouth (6, 9). Therefore, the device can be used in the same manner as a traditional laryngoscope, or indirectly by viewing the image on the screen. The video recorded can be later viewed by the trainers and learners, and can serve as one of the unique tools for future research in skill acquisition, competency assessment, and quality improvement in the neonatal intubation. The Food and Drug Administration have approved the C-MAC for use in neonates.

(Figure 3) Karl Storz C-Mac Video Laryngoscope

Over the past decade, there have been an increasing number of studies evaluating the effectiveness of simulation as educational tool (13) Simulation-based educational interventions increase retention of knowledge for resuscitation, trauma care, airway management, procedural skills team-training, and disaster management (14)
The intubation studies in the past have focused on the effectiveness of video laryngoscopy over direct laryngoscopy and the use of video laryngoscope for difficult intubations. However no studies have been done in order to identify the reason(s) behind variation in the training curve of novices and learners including pediatric residents. The question of why some learners require more time and more number of neonatal intubations to achieve proficiency is still unanswered.

Objective: To identify the specific problems in learning neonatal intubation by novices, by assessment of their intubation skill in a neonatal manikin (phase I) and real neonates in NICU (phase II) with the help of video laryngoscopy (Karl Storz C-MAC Video Laryngoscope).

Specific Aim:

1. Define novice vs. expert in neonatal intubation from procedural steps prospective, by studying video recording of learners' performing the procedure. Performance will be evaluated from two perspectives: external to the intubation head and inside the oral cavity using video laryngoscopy.
2. Identification of problem areas in learning neonatal intubation (e.g. anatomy, equipment, patient position)

Purpose:

1. Defining the steps required in achieving mastery in the procedure of neonatal intubation.
2. Development of the most effective and efficient training module of neonatal intubation.

Method: The study is planned in 2 phases which can occur in tandem,
<u>Phase I: Evaluation of performance in the simulated setting</u>
<u>Phase II: Evaluation of performance in the clinical setting</u>

Participants are practicing health care workers performing neonatal intubations as well as novice providers performing neonatal intubation. The participants will include Attending Neonatologists, Neonatal Fellows, Neonatal Nurse Practitioners, and Respiratory Therapists, pediatric residents, novice pediatric residents and interns. The participants (subjects) will be grouped in the following 3 categories according to their proficiency in performing neonatal intubations:

1. Experts: Neonatologists (attending physicians), senior neonatology fellows, NICU transport nurses, and experienced mid-level providers
2. Advance providers: Nurse Practitioners (ARNP), Respiratory therapists (RT) and Neonatology Fellows
3. Novices: Pediatric interns and residents, and other trainees (transport RN, NNP students)

We plan to study 20 intubations from each group of participants in both the phases. A total of 60 intubations will be studied in phase I and 60 intubations in phase II. The process of evaluating the procedural elements of the novice learners as compared to experts will be evaluated by cognitive task analysis (CTA). CTA has replaced traditional task analysis techniques to generate task demands as an input to training system design for many complex tasks. (15)

The study method will include following steps:

1. Pre-procedure assessment

All participants will be instructed to watch the New England Journal of Medicine Videos in Clinical Medicine on Orotracheal Intubation (16) to allow for an introduction to the airway anatomy and baseline understanding of the procedural technique. The details of the instrument and the neonatal manikin will be explained to each participant before performing the procedure. The participant will complete a self assessment questionnaire (Pre procedure subject form) **form no.1** to assess their knowledge and expertise in neonatal intubation

2. Procedural data collection

Phase I: Each participant will perform 2 intubations using Storz C-MAC by direct laryngoscopy, (not visualizing the video) in a neonatal manikin (for phase I) in the presence of a direct observer and an external video camera (recording the procedure). Video captured will be scored to characterize novice proceduralists for comparison to video of experts performing intubation on the same manikin.

Phase II: Trainees will perform neonatal intubations using Storz C-MAC by direct laryngoscopy, (performance will be recorded using the Storz device) in the NICU of Tampa General Hospital in the presence of a direct observer. Intubation procedure methods (patient choice, patient monitoring, supervision and assistance, and patient tolerance of procedure attempts) will not differ from current standard of care. In addition, the proceduralist's discipline and level of training will be documented. Recordings of successful and failed attempts will be evaluated for validation of novice and expert procedural technique determined in the simulation environment. The video images will not be available to the participant, but all the attempts will be recorded in order to describe the intubation process by the investigator.

Post-procedure assessment

Each participant will answer a self-assessment (post procedure subject form) **form no.2** to test and assess view of glottis during intubation attempt(s) and success of procedure.
In the simulation setting (Phase I), **form no.3** will be competed describing the intubation attempts including handling of equipment, time to intubate and no. of attempts

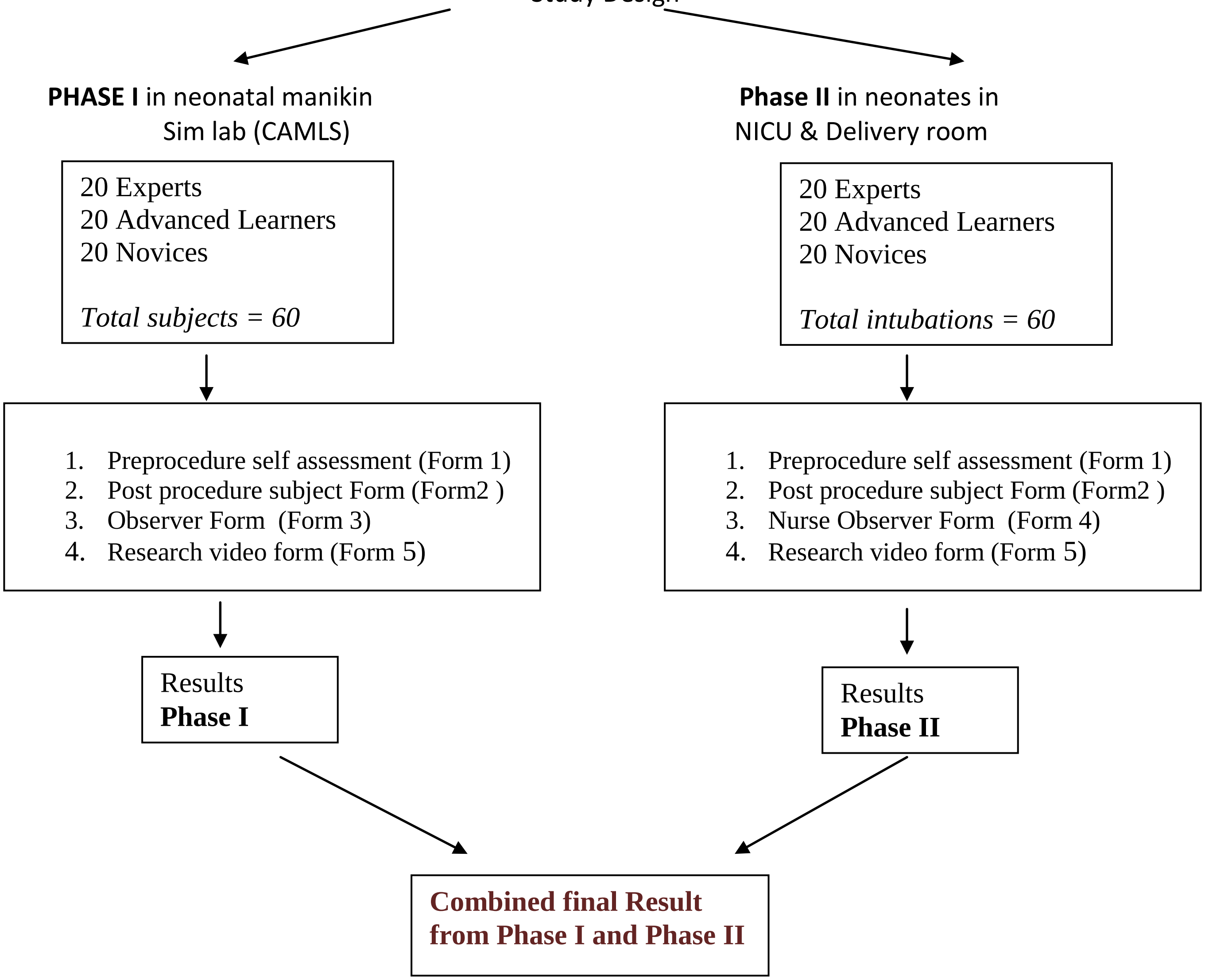
In the clinical setting (Phase 2), **form No.4** will be completed describing the details of the event in the live neonate, which will include the vital signs, patient characteristics and details of stabilization.

The investigator will score the video recording of the procedure technique (recorded using external camera). The video recording of each intubation attempt will show the procedure from inside the oropharynx. The investigator will now complete the (Investigator Video Form/ **form no.5)** based on video recordings from Storz C-MAC describing position of blade of laryngoscope and laryngeal anatomy visible during procedure.

Statistics and descriptive analysis

The data from all the forms will be collected and will be used for a descriptive analysis of the neonatal intubation by different health care workers. Sixty participants (20 from each group - 20 experts, 20 advanced learners and 20 novices) will be included in each phase I and phase II. It will require the capture of more than 60 intubations in the clinical setting to assure the proper distribution of experience in providers. The results from both the phase (I and II) will be used to identify the reason behind the variations in the learning curve of novices and differentiating experts from novices based on real time video recording of the procedure. Raters will score procedural performance using videotaped examples of the neonatal intubation (external and via video laryngoscope in the simulation lab; via video laryngoscope in the NICU). We will assess rater agreement using agreement statistics corrected by Cohn’s kappa for unequal base rates, considering 0.75 kappa to be acceptable agreement.

Study Design



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SAMPLE BUDGETS

Examples of Prior Grantee's Sample Budget Per Type of Research

Basic/ Translational Science

Immunohistochemical Characterization of Anaplastic Large Cell Lymphoma

Disclaimer: Max grant allotment is $5,000

Tissue Core Budget Planning Calculator				
	Cost Center	Rate	Number of Units	Total Cost
TMA sectioning and IHC				
TMA Microtomy- unstained slide	25842	$7.00	7	$49.00
Optimized Antibodies IHC-JAK1	25842	$42.00	1	$42.00
Optimized Antibodies IHC-STAT3	25842	$42.00	1	$42.00
Optimized Antibodies IHC-DUSP 22	25842	$42.00	1	$42.00
Optimized Antibodies IHC-BLIMP1/PRDM1	25842	$42.00	1	$42.00
Optimized Antibodies IHC-ERBB4 (Her4)	25842	$42.00	1	$42.00
Optimized Antibodies IHC-SOCS-3	25842	$42.00	1	$42.00
Optimized Antibodies IHC-PDGFR	25842	$42.00	1	$42.00
Single Stain Controls (Pos and Neg)	25842	$90.00	7	$630.00
Optimization: Single Stain- JAK 1	25842	$57.00	15	$855.00
Optimization: Single Stain- STAT3	25842	$57.00	15	$855.00
Optimization: Single Stain- DUSP 22	25842	$57.00	15	$855.00
Optimization: Single Stain- SOCS-3	25842	$57.00	15	$855.00
Antibody Purchase (7 antibodies)	25842	$57.00	15	$855.00
Chipboard Slide Holder	25842	$500.00	7	$3,500.00
	25842	$3.00	1	$3.00
			Estimated Total	**$8,751.00**

Disparity Projects:

Alleviating Burden of Chronic Disease (ABCD) among the Uninsured of Tampa Bay: USF Diabetes Intervention

	LINE ITEM BUDGET		
Item	Price	Quantity	Total Amount
Abbott Freestyle Glucometers (single)	$20.00	100	$2000.00
Test Strips (50 pack)	$50.00	60	$3000.00
		TOTAL	$5000.00

Total $5000.00 of funds would go toward the 'USF Grant Diabetes Kits for the Red Crescent Clinic. These kits would include glucometers and test strips for patients. Along with the diabetes kits, the patients will receive diabetes and food education from the health professionals that will volunteer at the monthly (Saturday) Endocrinology Clinic. Residents and medical students will together to recruit prospective patients into this program and they will be followed at appropriate intervals, post-intervention data analysis will be completed at 3-month intervals.

Quality Improvement Projects:

Who is on my team? Using baseball cards to improve patients' satisfaction through recognition and communication with their physician staff.

Budget justification:
36 Pediatric Residents
20 Internal Medicine-Pediatric Residents
4 Supervising Attendings
Total: 60 Physician "fun fact baseball cards"

Average cost of 100 multi-colored, double-sided baseball cards: $80 ($0.80 each)
Estimated total cost of 100 cards for each physician participating in study: $4,800 (shipping not included)
We are requesting the maximum $5,000 for this project.

Clinical Trials

Concurrent Hypertonic saline For Congestive heart failure Patients with and without Renal Syndrome I (CHF CPRS I)

Disclaimer: Max grant allotment is $5,000

PREPARATION	VA Employee (No additional Cost)
Sodium Chloride 3% Hypertonic Saline (case of 24)	$64.68
Sterile water 1000mL (case of 12)	$56.67
LABS	Send outlab per current VA policies on Research
Non standard BNPs for ~75 patients	Lab Corp quote ~70.00, for 75 patients ~5250.00
Subtotal	**$5371.35**