Final Progress Report for Research Projects Funded by Health Research Grants

Instructions: Please complete all of the items as instructed. Do not delete instructions. Do not leave any items blank; responses must be provided for all items. If your response to an item is "None", please specify "None" as your response. "Not applicable" is not an acceptable response for any of the items. There is no limit to the length of your response to any question. Responses should be single-spaced, no smaller than 12-point type. The report **must be completed using MS Word**. Submitted reports must be Word documents; they should not be converted to pdf format. Questions? Contact Health Research Program staff at 717-783-2548.

1. **Grantee Institution: Albert Einstein Healthcare Network**

2. **Reporting Period (start and end date of grant award period): 1/1/2009 – 6/30/2011**

3. **Grant Contact Person (First Name, M.I., Last Name, Degrees): Mary Klein, PhD**

4. **Grant Contact Person's Telephone Number: 215-456-7216**

5. **Grant SAP Number: 4100047622**

6. **Project Number and Title of Research Project: 02 – The Use of High Flow Oxygen During ED PSA with Propofol: A Randomized Trial**

7. **Start and End Date of Research Project: 1/1/2009 – 6/30/2011**

8. **Name of Principal Investigator for the Research Project: Kenneth Deitch, DO**

9. **Research Project Expenses**.

   9(A) Please provide the amount of health research grant funds spent on this project for the entire duration of the grant, including any interest earned that was spent:

   $23,280.81

   9(B) Provide the last names (include first initial if multiple individuals with the same last name are listed) of **all** persons who worked on this research project and were supported with health research funds. Include position titles (Principal Investigator, Graduate Assistant, Post-doctoral Fellow, etc.), percent of effort on project and total health research funds expended for the position. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project	Cost

Deitch	Director of Research	10%	$1,382
Chudnofsky	EM Dept. Chairman	10%	$1,382
Giraldo	Former Assoc. Dir. of Clinical Research	10%	$1,382
Mizrahi	Former Research Associate	10%	$1,382
Nino Oqroshidze	Former Research Associate	15%	$1,382
Mauricio Pedroza	Former Research Associate	10%	$1,382
Sorin Cadar	Former Research Associate	10%	$1,382
Kathia Damiron	Current Assoc. Dir. of Clinical Research	15%	$1,382
Yidy Salamanca	Former Research Associate	15%	$1,382
Dilys Ngu	Current Research Associate	10%	$1,382
Brendan Cooney	Current Research Associate	10%	$1,382
Nicole Piela	Current Research Associate	10%	$1,382

9(C) Provide the names of **all** persons who worked on this research project, but who *were not* supported with health research funds. Include position titles (Research Assistant, Administrative Assistant, etc.) and percent of effort on project. For multiple year projects, if percent of effort varied from year to year, report in the % of Effort column the effort by year 1, 2, 3, etc. of the project (x% Yr 1; z% Yr 2-3).

Last Name	Position Title	% of Effort on Project
Daniel Latta	Data analyst	15%
Paul Dominici	Data analyst	15%

9(D) Provide a list of **all** scientific equipment purchased as part of this research grant, a short description of the value (benefit) derived by the institution from this equipment, and the cost of the equipment.

Type of Scientific Equipment	Value Derived	Cost

10. Co-funding of Research Project during Health Research Grant Award Period. Did this research project receive funding from any other source during the project period when it was supported by the health research grant?

Yes____X_____ No_____

If yes, please indicate the source and amount of other funds:
Albert Einstein Society Research Grant, 2008: $16,593

11. Leveraging of Additional Funds

11(A) As a result of the health research funds provided for this research project, were you able to apply for and/or obtain funding from other sources to continue or expand the research?

Yes_____ No_____X____

If yes, please list the applications submitted (column A), the funding agency (National Institutes of Health—NIH, or other source in column B), the month and year when the application was submitted (column C), and the amount of funds requested (column D). If you have received a notice that the grant will be funded, please indicate the amount of funds to be awarded (column E). If the grant was not funded, insert "not funded" in column E.

Do not include funding from your own institution or from CURE (tobacco settlement funds). Do not include grants submitted prior to the start date of the grant as shown in Question 2. If you list grants submitted within 1-6 months of the start date of this grant, add a statement below the table indicating how the data/results from this project were used to secure that grant.

A. Title of research project on grant application	B. Funding agency (check those that apply)	C. Month and Year Submitted	D. Amount of funds requested:	E. Amount of funds to be awarded:
	☐NIH ☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)		$	$
	☐NIH ☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)		$	$
	☐NIH		$	$

	☐ Other federal (specify:_____ _____) ☐ Nonfederal source (specify: _____)			

11(B) Are you planning to apply for additional funding in the future to continue or expand the research?

Yes____X_____ No_____

If yes, please describe your plans: We are continuing to seek out alterative funding for a future line of capnography research from the American Pain society, The Anesthesia Safety and Pain society, and institutional grants from the Albert Einstein Society

12. **Future of Research Project.** What are the future plans for this research project?: We are submitting a study now evaluating pre-apenic respiratory patterns in procedural sedation, and another evaluating levels of respiratory depression in acute pain protocols in geriatric patients.

13. **New Investigator Training and Development**. Did students participate in project supported internships or graduate or post-graduate training for at least one semester or one summer?

Yes_____ No____X____

If yes, how many students? Please specify in the tables below:

	Undergraduate	Masters	Pre-doc	Post-doc
Male				
Female				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
Hispanic				
Non-Hispanic				
Unknown				
Total				

	Undergraduate	Masters	Pre-doc	Post-doc
White				
Black				

Asian				
Other				
Unknown				
Total				

14. **Recruitment of Out-of–State Researchers**. Did you bring researchers into Pennsylvania to carry out this research project?

    Yes_____ No____X_____

    If yes, please list the name and degree of each researcher and his/her previous affiliation:

15. **Impact on Research Capacity and Quality**. Did the health research project enhance the quality and/or capacity of research at your institution?

    Yes_____ No____X_____

    If yes, describe how improvements in infrastructure, the addition of new investigators, and other resources have led to more and better research.

16. **Collaboration, business and community involvement.**

    16(A) Did the health research funds lead to collaboration with research partners outside of your institution (e.g., entire university, entire hospital system)?

    Yes_____ No____X_____

    If yes, please describe the collaborations:

    16(B) Did the research project result in commercial development of any research products?

    Yes_____ No_____X_____

    If yes, please describe commercial development activities that resulted from the research project:

    16(C) Did the research lead to new involvement with the community?

    Yes_____ No___X_____

    If yes, please describe involvement with community groups that resulted from the research project:

17. Progress in Achieving Research Goals, Objectives and Aims.

List the project goals, objectives and specific aims (as contained in the grant application's strategic plan). Summarize the progress made in achieving these goals, objectives and aims for the entire grant award period. Indicate whether or not each goal/objective/aim was achieved; if something was not achieved, note the reasons why. Describe the methods used. If changes were made to the research goals/objectives/aims, methods, design or timeline since the original grant application was submitted, please describe the changes. Provide detailed results of the project. Include evidence of the data that was generated and analyzed, and provide tables, graphs, and figures of the data. List published abstracts, poster presentations and scientific meeting presentations at the end of the summary of progress; peer-reviewed publications should be listed under item 20.

This response should be a DETAILED report of the methods and findings. It is not sufficient to state that the work was completed. Insufficient information may result in an unfavorable performance review, which may jeopardize future funding. If research findings are pending publication you must still include enough detail for the expert peer reviewers to evaluate the progress during the course of the project.

Health research grants funded under the Tobacco Settlement Act will be evaluated via a performance review by an expert panel of researchers and clinicians who will assess project work using this Final Progress Report, all project Annual Reports and the project's strategic plan. After the final performance review of each project is complete, approximately 12-16 months after the end of the grant, this Final Progress Report, as well as the Final Performance Review Report containing the comments of the expert review panel, and the grantee's written response to the Final Performance Review Report, will be posted on the CURE Web site.

There is no limit to the length of your response. Responses must be single-spaced below, no smaller than 12-point type. If you cut and paste text from a publication, be sure symbols print properly, e.g., the Greek symbol for alpha (α) and beta (ß) should not print as boxes (□) and include the appropriate citation(s). DO NOT DELETE THESE INSTRUCTIONS.

Objectives: To determine if high flow oxygen reduces the incidence of hypoxia by 20% in adults receiving propofol for ED sedation compared to room air.

Methods: We randomized adults to receive 5 minutes of 100% oxygen or compressed air at 15 L/min via non-rebreather mask prior to and during propofol procedural sedation. We administered 1.0 mg/Kg of propofol followed by 0.5 mg/Kg boluses until the patient was adequately sedated. Physicians and patients were blinded to the gas used. Hypoxia was defined a priori as an oxygen saturation $\leq$93%; respiratory depression was defined as an end tidal CO_2 ($ETCO_2$) $\geq$50 mmHg, a 10% absolute change from baseline, or loss of waveform.

Results: We noted significantly less hypoxia in the 59 patients receiving high flow oxygen compared to the 58 receiving compressed air (19% versus 41%,,p=0.007, difference 23%, 95% CI 6%, 38%). Respiratory depression was similar between groups (51% versus 48%, difference 2%, 95% CI -15%, 22%). We observed 2 adverse events in the high flow group (1

hypotension, 1 bradycardia) and 2 in the compressed air group (1 assisted ventilation, 1 hypotension).

Conclusion: High flow oxygen reduces the frequency of hypoxia during ED propofol sedation in adults.

Background

Some emergency physicians administer supplemental oxygen during procedural sedation and analgesia to increase oxygen reserves and thus hopefully minimize the likelihood of hypoxia. The American Society of Anesthesiology and the American Academy of Pediatrics recommend supplemental oxygen for patients undergoing deep sedation, and suggest it be considered during moderate sedation. However, a previous trial of low flow nasal oxygen during emergency department (ED) propofol sedation did not identify a clinically significant reduction of hypoxia. High flow oxygen, however, is more likely to be beneficial because apnea with propofol develops and resolves quickly, and a healthy adult or adolescent when fully preoxygenated can tolerate on average 6 minutes of apnea prior to oxygen desaturation.

Importance

If high flow supplemental oxygen can reduce the incidence or severity of hypoxia during procedural sedation with propofol, it could be used routinely for this purpose.

Objectives

We wished to determine if high flow (15 L/minute) supplemental oxygen via non-rebreather mask reduces the incidence of hypoxia by 20% during ED propofol procedural sedation in adults. Our secondary objectives were to compare the frequencies of subclinical respiratory depression and other adverse events.

Study Design and Setting

We conducted this prospective, randomized, double blind, placebo-controlled study between January 2009 and November 2010 at the Albert Einstein Medical Center, a level one-trauma center in Philadelphia, PA with an annual census of approximately 100,000 visits. Our institutional review board approved the study, and informed consent was obtained.

Patients

We included adults ($\geq$18 years of age) chosen for propofol procedural sedation in accordance with our standard practice. We enrolled patients 24 hours a day, seven days a week during the study period. We excluded patients with severe chronic obstructive pulmonary disease, chronic oxygen use, hemodynamic instability, respiratory distress, pregnancy, allergy to any of the study drugs, or inability to provide informed consent.

Study Protocol

We used a computer-generated, concealed randomization schedule to assign patients to receive either high flow oxygen or room air, both administered at 15 liters per minute via a non-rebreather mask. The treatment team was blinded by delivering the gasses using one of two identical appearing D-tanks marked “A” and “B”. Patients wore a capnography nasal cannula under their mask, and received 5 minutes of gas administration prior to an initial propofol dose

of 1 mg/kg based on ideal body weight. The treating physician used their discretion to administer additional 0.5 mg/kg dose to achieve and maintain their desired level of sedation. The ED staff had standard electronic monitoring (capnography, pulse oximetry, heart rate, and blood pressure) available to them at all times, and applied their usual clinical judgment for monitoring and intervention for adverse events.

Blinded, separate research physicians enrolled patients and recorded data. These individuals had participated in previous sedation studies and were trained in procedural sedation, the study protocol, and the monitoring devices. They had no clinical responsibilities, and were instructed to observe and document but not interact with the clinical team or influence their actions.

Age, gender, past medical history, medications, and allergies; type of procedure performed; and sedation and procedure times were recorded by the research associates using a standardized data collection instrument. We defined elapsed procedure time as the time from initial propofol administration until the patient returned to baseline alertness.

Research associates recorded sedation depth using a six point Ramsay scale (1 point indicating agitation and 6 indicating unresponsiveness) at baseline, 90 seconds after completion of initial propofol administration, and at recovery. The capnography monitor used (Capnostream 20, Oridian, Needham MA) electronically records data every five seconds, and over the duration of each sedation research associates used electronic marking and time stamping to identify specific events, eg, drug administration, beginning and end of procedure, readiness for discharge. They also recorded the time and nature of any intervention for respiratory depression or hypoxia such as verbal or physical stimulation, airway realignment, use of additional oxygen, and the use of airway adjuncts, assisted ventilation, or intubation. They identified the occurrence of other adverse events including hypotension, bradycardia, arrhythmia, vomiting, prolonged ED stay, or admission.

Outcome measures

Our main study outcome was hypoxia, defined a priori as an oxygen saturation $\leq$93% for 15 seconds or greater. We defined a priori our secondary outcome of subclinical respiratory depression as an $ETCO_2$ level of 50 mmHg or greater, an absolute increase or decrease from baseline of 10% or greater, or a loss of waveform for 15 seconds or greater. To assess these outcomes, we downloaded electronic data from each sedation into a Microsoft Excel database, checked and adjudicated any discrepancies with research associate notations, and generated a graph of the patient's sedation with the X-axis showing time and the Y-axis depicting $ETCO_2$, SpO_2, respiratory rate, and heart rate. Electronic time stamps noted propofol administration, procedure initiation and completion, adverse events, and physician interventions.

Before study blinding was broken, three investigators evaluated each graph to code the presence or absence of hypoxia and respiratory depression. We disqualified graphs if they had >35% data loss, unless all three evaluators agreed that there was unequivocal evidence of hypoxia and/or respiratory depression. Lost data were typically due to patient movement (i.e., dislodgement of the cannula) or blood pressure cuff insufflations.

Data analysis

We analyzed our primary outcome with chi-square (assuming $p < 0.05$ as significant) and other outcomes descriptively using SPSS (SPSS, Chicago, Il). Assuming a 20% absolute reduction in hypoxia as clinically important, we calculated a sample size of 60 subjects in each group (alpha 0.05, power 81.5%).

RESULTS:

Patient flow is shown in Figure 1, and baseline characteristics were similar between groups (Table 1). Hypoxia was significantly less frequent with high flow oxygen; while capnographic respiratory depression was similar between groups (Table 2).

The breakdown of specific capnographic abnormalities was similar between groups for all patients with respiratory depression (Web Appendix A) and for the subset experiencing hypoxia (Web Appendix B). For patients with both respiratory depression and hypoxia (n=29), respiratory depression preceded hypoxia in all cases by a median of 45 seconds (IQR 29, 68), with these findings similar between groups. The frequency of physician intervention for respiratory depression and hypoxia was similar between groups (Table 3) and is detailed by study subject in Web Appendix C. When hypoxia was preceded by respiratory depression and an intervention occurred, the majority (13 out of 16) of the interventions occurred only after the patient developed hypoxia (Web Appendix C). When hypoxic patients did not receive an intervention, it was because their hypoxia was mild and transient (Web Appendix C).

Two adverse events occurred in the high flow oxygen group (1 bradycardia of 40 beats per minute lasting 5 minutes, 1 episode of hypotension to 80/50 mmHg that responded to IV fluids in 10 minutes). Two adverse events occurred in the compressed air group (1 assisted ventilation for 2 minutes, 1 hypotension to 85/40 mmHg that responded to IV fluids in 5 minutes). No patients were admitted as a result of these adverse events, and none were intubated.

LIMITATIONS

We defined hypoxia as an oxygen saturation of $\leq$93%, a threshold that we believe would prompt most clinicians to intervene to improve oxygenation and or ventilation Using the common threshold of 90% instead would have slightly decreased the incidence of hypoxia in our study, but not changed our outcome (15% high flow versus 36% compressed air, difference 21%, p=0.009, 95% CI 5%, 35%).

Physicians in this study had real time access to capnography as well as standard monitoring. Previous research has shown that the use of real time capnography during PSA allows clinicians to recognize respiratory depression very early and provide an intervention before an incidence of hypoxia can occur. 11 patients met criteria for respiratory depression in this study, received an intervention, and did not become hypoxic. It is conceivable that a proportion of these patients would have gone on to develop hypoxia. It is possible that our incidence of hypoxic events would have been even higher if we had not used capnography. We believe that the improved safety real time capnography provides should be part of routine practice, and thus would not be ethical to blind our clinicians.

DISCUSSION

In this first controlled trial of high flow supplemental oxygen (15 liters/minute) during ED propofol sedation, we found that this intervention decreased the incidence of hypoxia to a degree that was both statistically significantly and clinically important. We also reconfirmed our prior observation that capnography provided advance warning of hypoxic events. Thus, assuming that capnography is in place to monitor ventilatory function, our results strongly support the routine use of high flow oxygen during ED propofol sedation. Three prior non-blinded, non-randomized studies have compared sedated patients with and without supplemental

oxygen and found conflicting results with respect to respiratory depression and hypoxia. We have reported two prior controlled trials of low flow supplemental oxygen showing non-significant trends towards decreased hypoxia when sedating with midazolam and fentanyl and propofol, respectively. We found no difference between groups in the incidence of respiratory depression, confirming the findings of prior research that supplemental oxygen does not exacerbate respiratory depression.

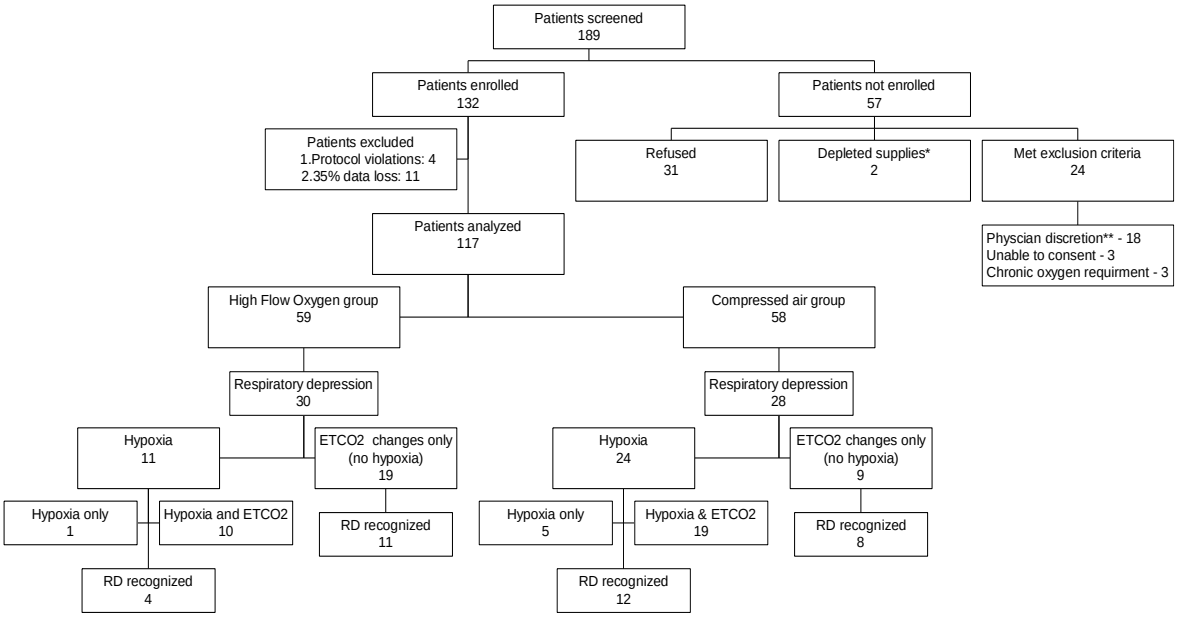
When our subjects experienced both respiratory depression and hypoxia, the respiratory depression always preceded the hypoxic event. However, in many cases the physicians chose not to intervene until the patient became hypoxic or did not intervene at all (see Web appendix C). We did not assess the physician rationale for delaying or withholding interventions, or whether these events were unrecognized altogether. The latter presumption would seem unlikely, given that our observed occurrences of hypoxia without an intervention were transient (Web appendix D).

Two of our studied capnographic patterns -- loss of waveform (apnea) and $ETCO_2$ >50 mmHg (type 1 or hypopneic respiratory depression) – most frequently heralded subsequent hypoxia (Web appendices A and B). Also, many patients in this study experienced respiratory depression that did not lead to hypoxia. Our study was not designed to assess the differential predictive value of the various capnographic patterns in predicting subsequent hypoxia, and this is a promising area for further research.

Capnography predicted in advance most hypoxic events in this study, in accordance with our previous sedation research. Such early warning may permit the treating physician to intervene, potentially preventing what would have otherwise led to a hypoxic event. However, we noted 5 patients in the compressed air group who developed hypoxia without preceding respiratory depression, and thus capnography cannot be completely relied upon in this setting. Patients who receive supplemental oxygen will have greater shift of their oxygen desaturation curves and thus may develop profound respiratory depression yet never go on to a hypoxic event. Patients breathing atmospheric oxygen, on the other hand, do not have this shift of the oxygen desaturation curves, and thus may desaturate without developing capnographic evidence of respiratory depression.

In summary, we found that high flow supplemental oxygen significantly reduced the incidence of hypoxia during ED propofol sedation. We believe that such supplementation should be routinely administered, assuming the presence of capnography to monitoring ventilations.

Figure 1: Schematic representation of study results.



*Depleted supplies: Ran out of nasal cannula

**Physician discretion: Physician felt that the patient was not a candidate for procedural sedation or propofol

RD = respiratory depression

Table 1. Patient Characteristics

	High Flow Oxygen (n=59)	**Compressed Air (n=58)**
Median age (Yrs)	37 (IQR: 27, 55)	32 (IQR: 21.5, 45.5)
Gender (# of Female)	35 (59% 95% CI: 46, 72)	28 (48% 95% CI:35, 61)

Median weight (Kg)	77 (IQR: 68, 95)	86 (IQR: 74, 95)
Abscess I & D (%)	42 (95% CI: 29, 55)	51 (95% CI: 38, 64)
Fracture reduction (%)	11 (95% CI: 3, 19)	17 (95% CI:7, 27)
Joint reduction (%)	47 (95% CI: 34, 60)	32 (95% CI: 20, 44)
Median initial propofol dose (mg/Kg)	1.0 (IQR: 1.0, 1.0)	1.0 (IQR: 1.0, 1.0)
Median total propofol dose (mg/Kg)	1.6 (IQR: 1.1, 2.8)	1.5 (IQR: 1.0, 2.0)
Median Ramsey scores (90 seconds after the last dose of pre-procedure propofol)	4 (IQR: 2, 5)	4 (IQR: 2, 5)
Median time from first dose of propofol to return to baseline alertness (minutes)	14 (IQR: 10, 19)	15 (IQR: 11, 23)

Table 2. Respiratory Depression and Hypoxia

	High Flow Oxygen (n=59)	**Compressed Air (n=58)**	**Difference (95% CI)**
# Patients who developed hypoxia	11 (19%)	24 (41%)	23% p=0.007 (95% CI= 6%, 38%)
Respiratory depression	30 (51%)	28 (48%)	3% (-16%, 21%)
Hypoxia	10 (17%)	19 (33%)	16% (1%, 31%)
No hypoxia	20 (34%)	9 (16%)	18%(3%, 33%)
No respiratory depression	29 (49%)	30 (52%)	3% (-21%, 16%)
Hypoxia	1 (2%)	5 (9%)	7% (-15%, 1%)
No hypoxia	28 (48%)	25 (43%)	4% (-14%, 22%)

Table 3. Interventions and Hypoxia/Respiratory Depression.

Intervention/No Intervention	**High Flow Oxygen (N=59)**	**Compressed Air (N=58)**	**Effect Size (95% CI)**
Hypoxia, Intervention	6	13	12% (-1%, 25%)
No hypoxia, Intervention	6	5	1% (-9%, 13%)
Hypoxia, No intervention	5	11	8% (-4%, 20%)
No hypoxia, No intervention	42	30	19% (2%, 35%)

Table D: Patients that developed hypoxia and did not receive an intervention

RD criteria		Hypoxia	Elapsed time between onset of RD and onset of hypoxia; when it occurred	How long was the patient hypoxic
High Flow Group				
1	Above 50 mmHg	87%	35 sec, after	20 sec
2	Loss of waveform	89%	100 sec, after	30 sec
3	Loss of waveform	89%	10 sec, after	20 sec
4	10% below baseline	92%	35 sec, after	15 sec
5	10 % below baseline	93%	50 sec, after	20 sec
Compressed air group				
1	Above 50 mmHg	93%	35 sec, after	15 sec
2	Above 50 mmHg	85%	50 sec, same time	30 sec
3	Loss of waveform	89%	15 sec, after	20 sec
4	Loss of waveform	85%	35 sec	20 sec
5	10% change above baseline	79%	50 sec, after	25 sec
6	10% below baseline	87%	50 sec, after	20 sec
7	10% change below baseline	89%	20 sec, after	20 sec
8	10 % change above baseline	90%	120 sec, after	25 sec
9	none	79%	n/a	35 sec
10	none	80%	n/a	20 sec
11	none	89%	n/a	25 sec

Distribution of capnographic abnormalities in patients with respiratory depression *

Web appendix A:ETCO2 Changes, Description

$ETCO_2$ changes	**High Flow Oxygen (n=30)**	**Compressed Air (N=28)**	**Effect Size with 95% CI (%)**
$ETCO_2$ ≥10% above baseline, ≥50 mmHg	7	8	5% (-28%, 17%)
$ETCO_2$ ≥10% below baseline, loss of waveform	9	8	5% (-28%, 17%)
$ETCO_2$ ≥10% below baseline	11	9	5% (-20%, 29%)
$ETCO_2$ ≥10% above baseline	3	3	6% (-12%, 24%)
No ETCO2 changes	29	30	3% (-21%, 16%)

Web appendix B: Relationship of capnographic abnormalities to hypoxic events

$ETCO_2$ changes	**Resulting hypoxia: High flow (N=11)**	**Resulting hypoxia: Compressed air (N=24)**	**Effect size and 95% CI (%)**
$ETCO_2$ ≥10% above baseline, ≥50 mmHg	3	8	5% (-27%, 32%)
$ETCO_2$ ≥10% below baseline, loss of waveform	4	8	3% (-26%, 35%)
$ETCO_2$ ≥10% below baseline	3	2	19% (-5%, 40%)
$ETCO_2$ ≥10% above baseline	0	1	4%(-21%, 20%)
No ETCO2 changes	1	5	11% (-19%, 33%)

Web appendix C: Respiratory Depression Criteria, Relationship To Hypoxic Events

Respiratory Depression Criteria		**Hypoxia**	**Time from onset of RD to onset of hypoxia**	**Intervention**	**When intervention occurred relative to hypoxia**
High Flow Group					
1	10% below baseline	88%	45 sec, after	Airway repositioning	Same time
2	10% below baseline	none	n/a	Verbal/painful stim	n/a
3	Loss of waveform	none	n/a	Verbal stim/airway repos	n/a
4	Loss of waveform	85%	45 sec, after	Airway repositioning	Same time
5	Loss of waveform	none	n/a	Airway repo/painful stim	n/a
6	Loss of waveform	none	n/a	Airway repositioning	n/a
7	Loss of waveform	83%	65 sec, after	Airway repositioning	25 sec before
8	Loss of waveform	none	n/a	Airwayrepositioning/ verbal/painful stim	n/a
9	Loss of waveform	none	n/a	Airway repositioning	n/a
10	Above 50 mmHg	85%	40 sec, after	Airway repositioning	10 sec before
11	Above 50 mmHg	60%	30 sec, after	Wall oxygen	Same time
12	None	90%	n/a	Wall oxygen	n/a
Compressed Air group					
1	10% below baseline	none	n/a	Wall oxygen	n/a
2	10% below baseline	75%	50 sec, after	Wall oxygen	Same time
3	10% below baseline	79%	75 sec, after	Airway repositioning	Same time
4	10% below baseline	88%	20 sec, after	Wall oxygen	Same time
5	10% below baseline	none	n/a	Verbal/Painful stim	n/a
6	10% below baseline	60%	120 sec, after	Airway repositioning/BVM	Same time
7	10% below baseline	80 %	75 sec, after	Airway repositioning	Same time
8	Greater than 50 mmHg /Loss of waveform	none	n/a	Verbal stim/Airway repositioning	n/a
9	Greater than 50 mmHg /Loss of waveform	89%	25 sec, after	Verbal/Painful stim/Wall oxygen	Same time
10	Loss of waveform	83%	10 sec, after	Airway repositioning	Same time
11	Loss of waveform	91%	50 sec, after	Airway repositioning	Same time
12	Loss of waveform	none	n/a	Verbal/Painful stim	n/a

13	Loss of waveform	none	n/a	Verbal/Painful stim	n/a
14	Above 50 mmHg	87%	35 sec, after	Painful stim	Same time
15	Above 50 mmHg	88%	75 sec, after	Airway repositioning	Same time
16	Above 50 mmHg	87%	80 sec, after	Wall oxygen	25 sec before
17	None	88%	n/a	Wall oxygen	n/a
18	None	88%	n/a	Wall oxygen	n/a
19	None	93%	n/a	Verbal stim	n/a

18. Extent of Clinical Activities Initiated and Completed. Items 18(A) and 18(B) should be completed for all research projects. If the project was restricted to secondary analysis of clinical data or data analysis of clinical research, then responses to 18(A) and 18(B) should be "No."

18(A) Did you initiate a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

__X__Yes
_____No

18(B) Did you complete a study that involved the testing of treatment, prevention or diagnostic procedures on human subjects?

___X ___Yes
_____No

If "Yes" to either 18(A) or 18(B), items 18(C) – (F) must also be completed. (Do NOT complete 18(C-F) if 18(A) and 18(B) are both "No.")

18(C) How many hospital and health care professionals were involved in the research project?

___50__ plus_Number of hospital and health care professionals involved in the research project

18(D) How many subjects were included in the study compared to targeted goals?

___120___Number of subjects originally targeted to be included in the study
___132___Number of subjects enrolled in the study

Note: Studies that fall dramatically short on recruitment are encouraged to provide the details of their recruitment efforts in Item 17, Progress in Achieving Research Goals, Objectives and Aims. For example, the number of eligible subjects approached the number that refused to participate and the reasons for refusal. Without this information it is difficult to discern whether eligibility criteria were too restrictive or the study simply did not appeal to subjects.

18(E) How many subjects were enrolled in the study by gender, ethnicity and race?

Gender:
___67__Males
___65__Females
___0___Unknown

Ethnicity:
_____Latinos or Hispanics
_____ Not Latinos or Hispanics
___X__Unknown

Race:
_____American Indian or Alaska Native
_____Asian
_____Blacks or African American
_____Native Hawaiian or Other Pacific Islander
_____White
_____Other, specify:_____
__X__ Unknown

18(F) Where was the research study conducted? (List the county where the research study was conducted. If the treatment, prevention and diagnostic tests were offered in more than one county, list all of the counties where the research study was conducted.) Albert Einstein Medical Center, Philadelphia, PA

19. Human Embryonic Stem Cell Research. Item 19(A) should be completed for all research projects. If the research project involved human embryonic stem cells, items 19(B) and 19(C) must also be completed.

19(A) Did this project involves, in any capacity, human embryonic stem cells?
_____Yes
__X__ No

19(B) Were these stem cell lines NIH-approved lines that were derived outside of Pennsylvania?
_____Yes
_____ No

19(C) Please describe how this project involved human embryonic stem cells:

20. Articles Submitted to Peer-Reviewed Publications.

20(A) Identify all publications that resulted from the research performed during the funding period and that have been submitted to peer-reviewed publications. Do not list journal abstracts or presentations at professional meetings; abstract and meeting presentations should be listed at the end of item 17. **Include only those publications that acknowledge the Pennsylvania Department of Health as a funding source** (as required in the grant agreement). List the title of the journal article, the authors, the name of the peer-reviewed publication, the month and year when it was submitted, and the status of publication (submitted for publication, accepted for publication or published.). Submit an electronic copy of each publication, listed in the table, in a PDF version 5.0.5 format, 1,200 dpi. Filenames for each publication should include the number of the research project, the last name of the PI, the number of the publication and an abbreviated research project title. For example, if you submit two publications for PI Smith for the "Cognition and MRI in Older Adults" research project (Project 1), and two publications for PI Zhang for the "Lung Cancer" research project (Project 3), the filenames should be:

Project 1 – Smith – Publication 1 – Cognition and MRI
Project 1 – Smith – Publication 2 – Cognition and MRI
Project 3 – Zhang – Publication 1 – Lung Cancer
Project 3 – Zhang – Publication 2 – Lung Cancer

If the publication is not available electronically, provide 5 paper copies of the publication.

Note: The grant agreement requires that recipients acknowledge the Pennsylvania Department of Health funding in all publications. Please ensure that all publications listed acknowledge the Department of Health funding. If a publication does not acknowledge the funding from the Commonwealth, do not list the publication.

Title of Journal Article:	Authors:	Name of Peer-reviewed Publication:	Month and Year Submitted:	Publication Status (check appropriate box below):
1.The utility of high flow supplemental oxygen duing procedural sedation with propofol, a randomized controlled trial	Deitch K, Chudnofsky C, Dominici P, et al	Annals of Emergency Medicine		☐Submitted ☐Accepted X Published
2.				☐Submitted ☐Accepted ☐Published
3.				☐Submitted ☐Accepted ☐Published

20(B) Based on this project, are you planning to submit articles to peer-reviewed publications in the future?

Yes __X_____ No_____

If yes, please describe your plans: See continued line of research

21. Changes in Outcome, Impact and Effectiveness Attributable to the Research Project. Describe the outcome, impact, and effectiveness of the research project by summarizing its impact on the incidence of disease, death from disease, stage of disease at time of diagnosis, or other relevant measures of outcome, impact or effectiveness of the research project. If there were no changes, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

The impact on sedation practice in the ED, and other venues where procedural sedation occurs is large. 100% oxygen given in high flow protocols, clearly demonstrates a safety benefit over room air, and does not mask respiratory depression with propofol. It should be part of routine sedation practice.

22. Major Discoveries, New Drugs, and New Approaches for Prevention Diagnosis and Treatment. Describe major discoveries, new drugs, and new approaches for prevention, diagnosis and treatment that are attributable to the completed research project. If there were no major discoveries, drugs or approaches, insert "None"; do not use "Not applicable." Responses must be single-spaced below, and no smaller than 12-point type. DO NOT DELETE THESE INSTRUCTIONS. There is no limit to the length of your response.

None

23. Inventions, Patents and Commercial Development Opportunities.

23(A) Were any inventions, which may be patentable or otherwise protectable under Title 35 of the United States Code, conceived or first actually reduced to practice in the performance of work under this health research grant? Yes_____ No___X_____

If "Yes" to 23(A), complete items a – g below for each invention. (Do NOT complete items a - g if 23(A) is "No.")

a. Title of Invention:

b. Name of Inventor(s):

c. Technical Description of Invention (describe nature, purpose, operation and physical, chemical, biological or electrical characteristics of the invention):

d. Was a patent filed for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____

If yes, indicate date patent was filed:

e. Was a patent issued for the invention conceived or first actually reduced to practice in the performance of work under this health research grant?
Yes_____ No____
If yes, indicate number of patent, title and date issued:
Patent number:
Title of patent:
Date issued:

f. Were any licenses granted for the patent obtained as a result of work performed under this health research grant? Yes_____ No____

If yes, how many licenses were granted?_____

g. Were any commercial development activities taken to develop the invention into a commercial product or service for manufacture or sale? Yes_____ No____

If yes, describe the commercial development activities:

23(B) Based on the results of this project, are you planning to file for any licenses or patents, or undertake any commercial development opportunities in the future?

Yes_____ No___X____

If yes, please describe your plans:

24. Key Investigator Qualifications. Briefly describe the education, research interests and experience and professional commitments of the Principal Investigator and all other key investigators. In place of narrative you may insert the NIH biosketch form here; however, please limit each biosketch to 1-2 pages. *For Nonformula grants only – include information for only those key investigators whose biosketches were not included in the original grant application.*

Principal Investigator/Program Director *(Last, first, middle):* Deitch, Ken

BIOGRAPHICAL SKETCH

Provide the following information for the key personnel in the order listed for Form Page 2.
Follow this format for each person. **DO NOT EXCEED FOUR PAGES.**

NAME	POSITION TITLE
Ken Deitch D.O.	Attending Physician, Department of Emergency Medicine Albert Einstein Medical Center Philadelphia, PA

EDUCATION/TRAINING *(Begin with baccalaureate or other initial professional education, such as nursing, and include postdoctoral training.)*

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
St. Lawrence University, Canton, NY	BA	1992	Government
Western University Of Health Sciences	DO	1999	Medicine
Albert Einstein Medical Center-Residency		2003	Emergency Medicine

A. Positions and Honors.

a. EMBRS research fellowship, ACEP, Fall/Spring 2004/2005

b. Attending Physician, Department of Emergency Medicine, Albert Einstein Medical Center July 2003 topresent

c. Medical staff board member, Albert Einstein Medical Center, 2004 to present

d. Resident Physician, Department of Emergency Medicine, Albert Einstein Medical Center July 1999-June 2003

B: Professional Memberships:

2004-present: Diplomate, American Board of Emergency Medicine
1999:present: Member, American College of Emergency Physicians
1999-present: Member, Society of Academic Emergency Medicine

C: Research experience:

- ***The Use of Supplemental Oxygen in Emergency Department Procedural Sedation; A Randomized, Controlled Trial:*** Deitch K, Chudnofsky CR, Domenci P. Manuscript accepted for publication, Annals of Emergency Medicine, date pending. Abstract accepted, poster presented, Scientific convention, ACEP September 2005. Annals of Emergency Medicine, October 2005.
- ***The Use of Supplemental Oxygen in Emergency Department Procedural Sedation with Propofol, a Randomized, Controlled Trial:*** Deitch K, Chudnofsky CR, Domenci P. Currently enrolling patients, Winter 2005-2006.
- ***Thoracic Disc Herniation with Myelopathy:*** Deitch K, Chudnofsky CR, Young M. Case report, accepted pending revisions, American Journal of Emergency Medicine Spring 2005.
- ***External Validation of the Mortality in Emergency Department Sepsis (MEDS) Score: A Multi-Center Prospective Cohort Study,*** J. Sankoff, M. Goyal, D. F. Gaieski, **K. Deitch**, J. Haukoos. **Abstract accepted, poster presentation ACEP scientific assembly Fall 2006**

- ***Predictive Accuracy of a Sepsis-Related Mortality Score in the Emergency Department: A Modification of the Mortality in Emergency Department Sepsis (MEDS) Score*****:** J. Sankoff, **K.**

Deitch, M. Goyal, D. F. Gaieski, J. Haukoos **Abstract accepted, poster presentation ACEP scientific assembly Fall 2006**

- ***Prospective Validiation of the Goldfrank Sniffing Bar for Identification of Toxic Odors:*** O'Malley G, Young M, Deitch K. Abstract accepted for poster presentation, SAEM 2005. Manuscript pending.

- ***The Use of Topical Diclofenac (0.3%) in acute ankle sprain, a randomized, placebo controlled trial:*** Deitch, K, Chudnofsky, CR. Investigator IND will be presented to the FDA February 2006, study presented to and accepted by IRB February, 2005.

- ***Youth Violence Recidivism Among ED Patients***. Deitch K, Sorondo B, Lane P, Fisher J, Mallalieu J, Mallalieu R, Nguyen T. Annals of Emergency Medicine; 42(4) October, 2003 in press Abstract accepted as moderated poster at ACEP Scientific Assembly 2003, October 13, 2003, Boston, MA. It was presented at Sixth Annual Mid-Atlantic Regional SAEM Research Meeting on March 15, 2003 at George Washington U. in D.C..