# VENTOR Study

## Focus Group Discussion with Medical Care Providers

By Rohin Singla PGY-5

Mentored by Dr. Patel

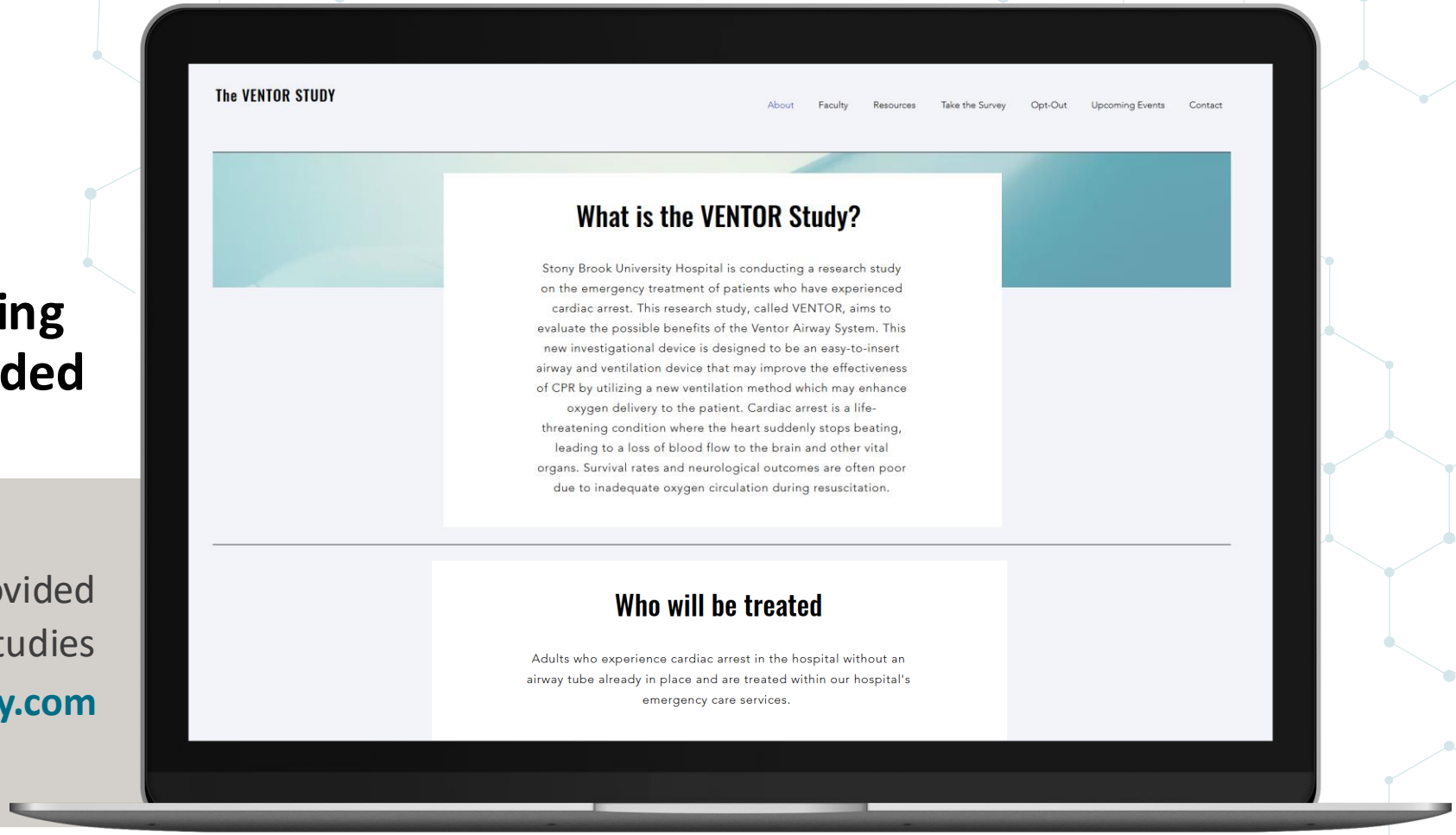
# House Keeping Items

REC

**Today's meeting is being recorded**

All of today's materials seen/provided today can be found at the studies

**www.ventorstudy.com**



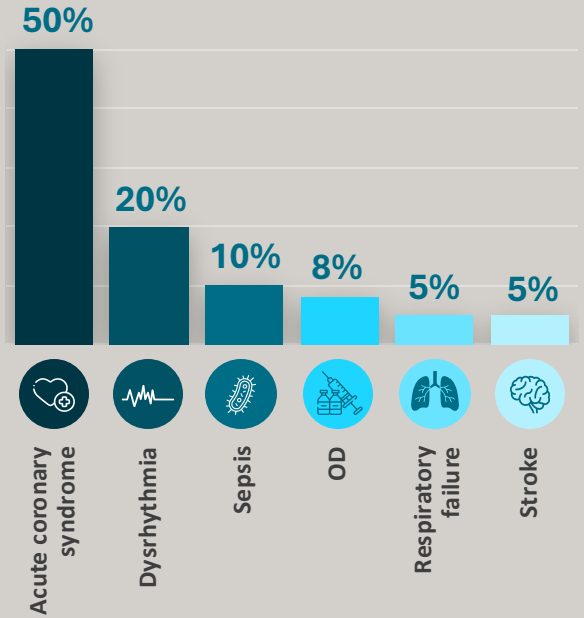
# Today's Agenda

1. Current resuscitation guidelines and priorities during CPR
2. Discuss the optimal ventilation strategy during CPR
3. Introduction of the Ventor Airway System
4. Review the VENTOR study design
5. Exception From Informed Consent criteria
6. Discussion

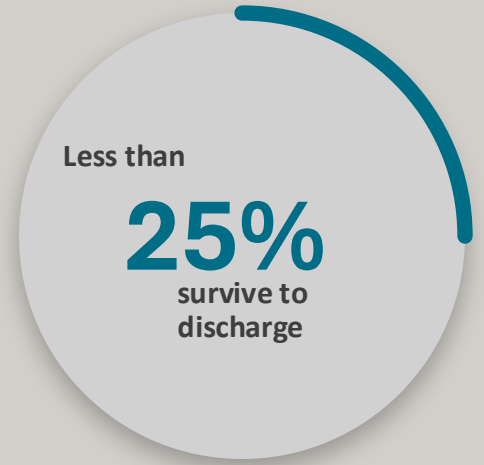
# Room to improve cardiac arrest survival

"Annually 290,000 patients in the U.S. face in-hospital cardiac arrest."


## Causes of arrest vary from:

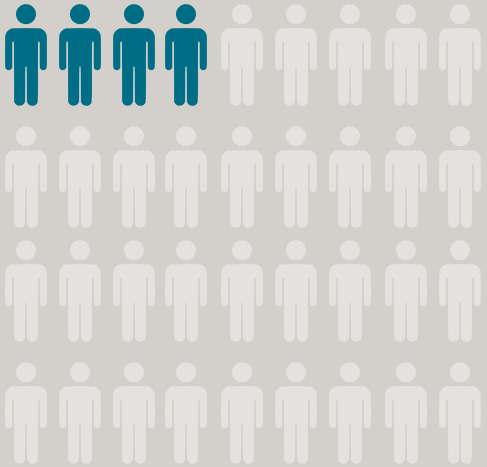



## In-Hospital Cardiac Arrest Survival Rates




## Of Which

**Only Half Will Have Good Neurological Outcomes**



# The American Heart Association emphasizes compressions over airway and ventilation, starting with BLS.

## C – A – B

### Compression

Push hard and fast on the center of the victim's chest.

### Airway

Tilt the victim's head back and lift the chin to open the airway.

### Breathing

Give mouth-to-mouth rescue breaths.

American Heart Association.

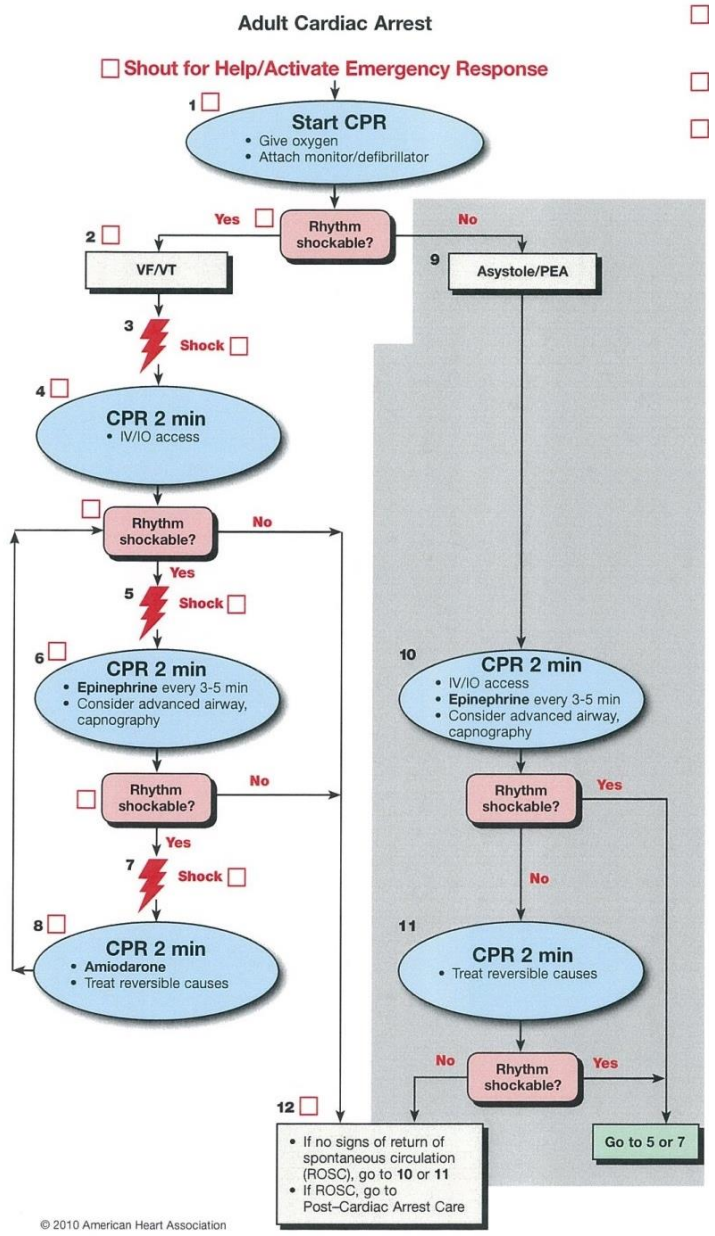
*Learn and Live*

# The AHA has also deemphasized airway management for ACLS care providers.

## Current AHA Treatment Modality Priority:

1. Start CPR
2. Give Oxygen
3. Defibrillate (if shockable rhythm)
4. IV/IO Access
5. Give Epi
6. **Consider** Advanced Airway placement

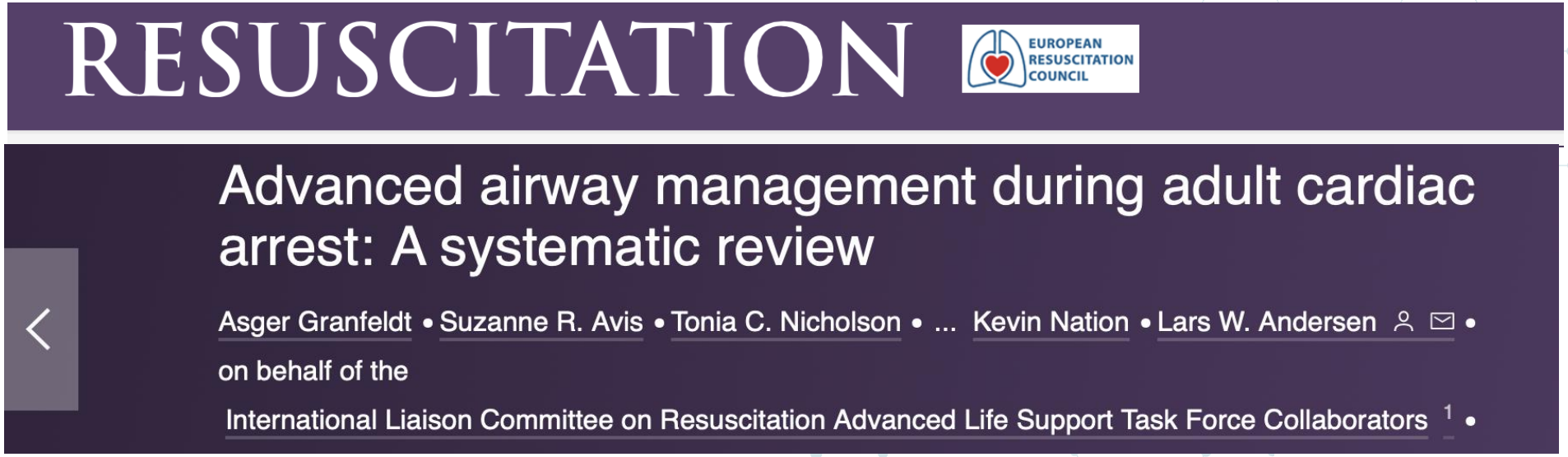
**Advanced Airway**
- Supraglottic advanced airway or endotracheal intubation
- Waveform capnography to confirm and monitor ET tube placement
- 8-10 breaths per minute with continuous chest compressions



# Why does the AHA continue to deemphasize airway and ventilation?

- **Is ventilation during CPR not important?**
- **Is ventilation too difficult to perform correctly, potentially diverting focus from other critical care?**

# What does research suggest:




## AIM

To systematically review literature on advanced airway management during adult cardiac arrest to inform the International Liaison Committee of Resuscitation (ILCOR) consensus on science and treatment recommendations.

## METHODS

- Review followed PRISMA guidelines and registered on PROSPERO
- Databases searched: Medline, Embase, and Evidence-Based Medicine Reviews (studies before Oct 30, 2018).
- Focus: Adult cardiac arrest patients.

Two investigators:

- Reviewed study relevance
- Extracted data
- Assessed bias risk

# Systematically reviewing airway management during adult cardiac arrest found:

## RESULTS

**Studies Included:**

- 78 observational and 11 controlled trials (focused on out-of-hospital cardiac arrest).

**Key Comparisons in Trials:**

- Supraglottic airway vs. tracheal intubation.
- Bag-mask ventilation vs. tracheal intubation.

**Conclusion:**

- Clinical and methodological variability prevented meaningful meta-analyses.

## CONCLUSIONS

Identified a large number of studies related to advanced airway management in adult cardiac arrest. Three recently published, large randomized trials in out-of-hospital cardiac arrest will help to inform future guidelines. **Trials of advanced airway management during in-hospital cardiac arrest are lacking**.

# What can we glean from the current research?

- **Importance of ventilation during CPR**
- **Difficulties of providing BVM ventilations and emergency intubation.**

# Bag-Valve-Mask Ventilation and Survival From Out-of-Hospital Cardiac Arrest: A Multicenter Study

Circulation: Dec 2023

## BACKGROUND:

Few studies have assessed ventilation during early CPR before advanced airway placement. While guidelines recommend pausing after 30 compressions for ventilations, the effectiveness of bag-valve-mask ventilation remains unknown.

## Sought to determine:

- The incidence of lung inflation with professional bag-valve-mask ventilation during 30:2 CPR;
- The association of ventilation with outcomes after out-of-hospital cardiac arrest.

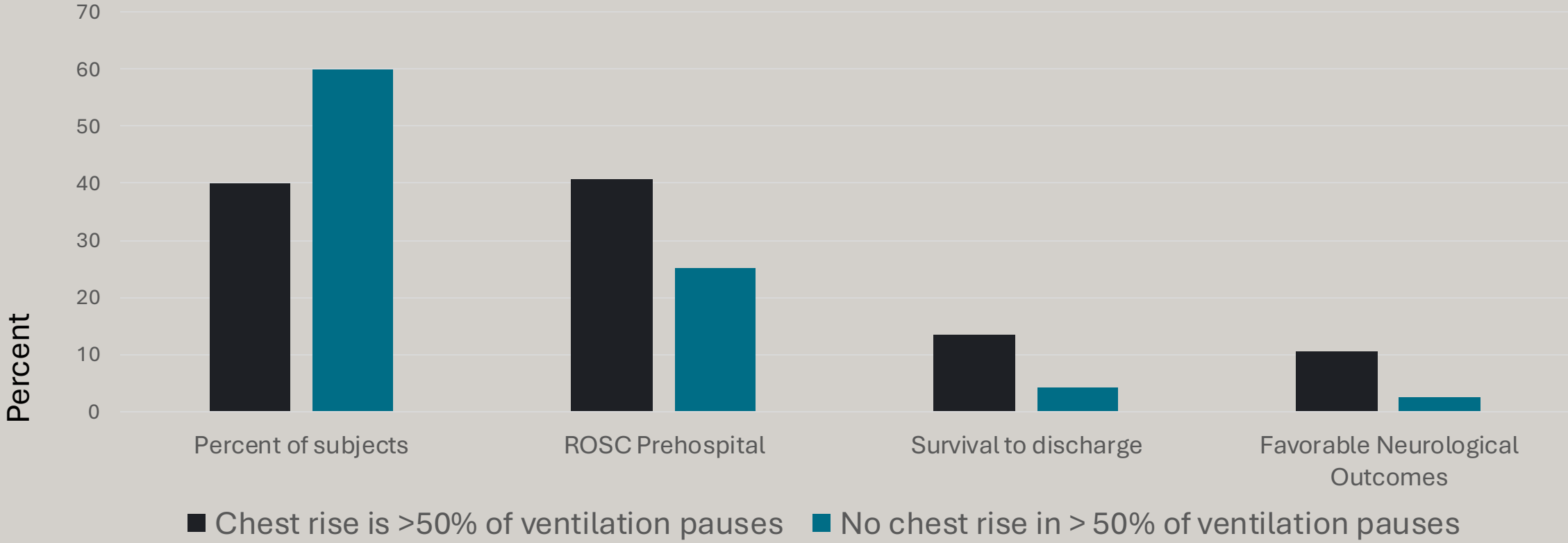
# Bag-Valve-Mask Ventilation and Survival From Out-of-Hospital Cardiac Arrest: A Multicenter Study

Circulation: Dec 2023

## RESULTS:

**Population:**
1,976 patients; mean age: 65 years

**CPR Duration:**
Mean ± SD duration of 30:2 CPR before advanced airway placement: **9.8 ± 4.9 min**.



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# Association of Arterial Oxygen Tension During In-Hospital Cardiac Arrest With Return of Spontaneous Circulation and Survival

Jignesh K. Patel, MD[1], Elinor Schoenfeld, PhD[2], Puja B. Parikh, MD, MPH[3], and Sam Parnia, MD, PhD[1]

## BACKGROUND

IHCA remains linked to high morbidity and mortality despite advances.

## Study goal:

Assess impact of arterial oxygen tension ($PaO_2$) on ROSC and survival to discharge in IHCA patients.

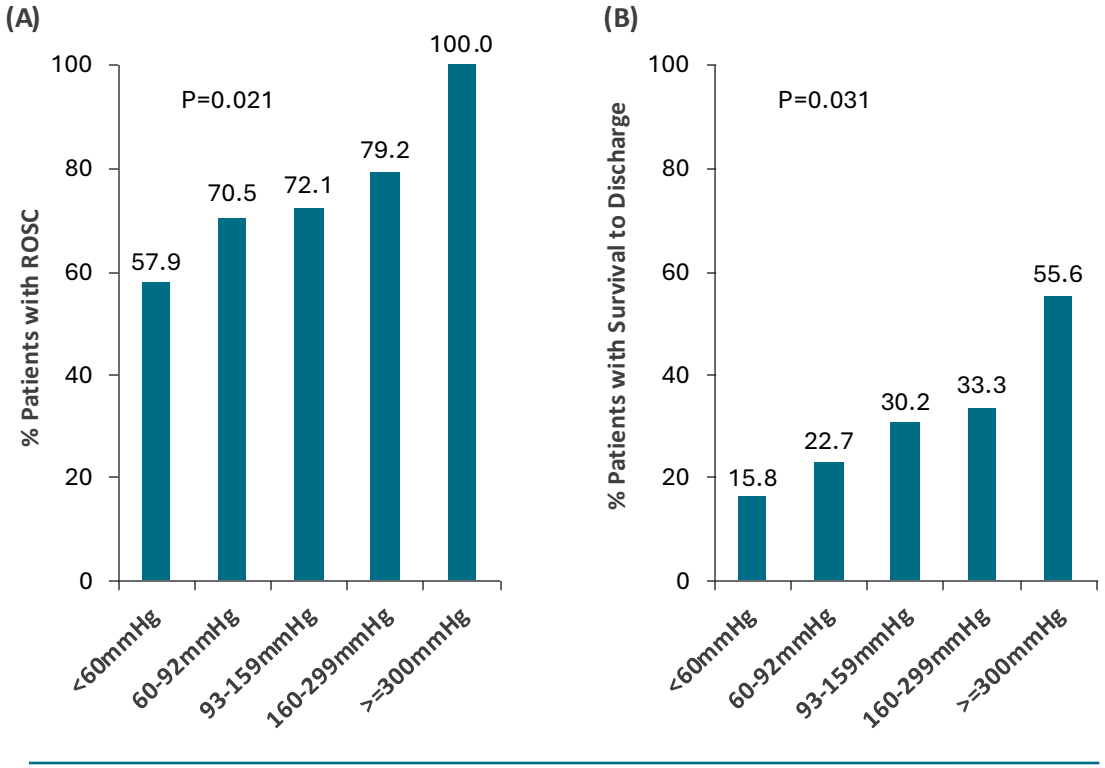
## METHODS:

**255 IHCA patients**, January 2012 - December 2013.

- 167 had arterial blood gas tested during arrest.

Primary outcome:

- Survival to discharge; Secondary: ROSC.




Rates of:

**(A)** return of spontaneous circulation (ROSC) and

**(B)** survival to hospital discharge according to $PaO_2$ group in adults with in-hospital cardiac arrest.

## Multivariate Analysis of Predictors of Survival to Discharge.[a]

| | Odds Ratio | 95% CI | *P* Value |
|---|---|---|---|
| $PaO_2$ < 60mm Hg (referent) | - | - | - |
| 60 mm Hg ≤ $PaO_2$ < 93 mm Hg | 3.95 | 0.44-35.40 | .220 |
| 93 mm Hg ≤ $PaO_2$ < 160 mm Hg | 6.79 | 0.83-55.76 | .075 |
| 160mm Hg ≤ $PaO_2$ < 300 mm Hg | 8.70 | 0.63-120.26 | .106 |
| $PaO_2$ ≥ 300 mm Hg | 60.68 | 3.04-1210.28 | .007 |

Abbreviation: CI, confidence interval.
[a]Variables included in the model: $PaO_2$ group, age, initial rhythm, chronic obstructive pulmonary disease, serum potassium, arterial pH, arterial $PaO_2$, and serum blood urea nitrogen.

## CONCLUSIONS:

Higher oxygenation ($PaO_2$) is correlated with improved survival.

Unclear if $PaO_2$ variation is due to patient condition, CPR quality, or ventilation effectiveness.

# Why ventilation during CPR is important?

- Oxygen stores deplete within first few minutes of cardiac arrest, leads to ischemic damage
- Lower survival associated with compression only CPR
- Want to achieve balance between adequate oxygenation and $CO_2$ removal while avoiding adverse hemodynamic effects of ventilation

# Association Between Tracheal Intubation During Adult In-Hospital Cardiac Arrest and Survival

Lars W. Andersen, MD, MPH, American Heart Association's Get With The Guidelines-Resuscitation Investigators

## IMPORTANCE

Tracheal intubation is common in adult IHCA, but its impact on survival is unclear.

## OBJECTIVE

Assess whether tracheal intubation during IHCA affects survival to discharge.

## DESIGN & PARTICIPANTS

- Observational cohort of adults in IHCA (n=108,079)
- Excluded patients with pre-existing invasive airway.
- Matched intubated and non-intubated patients using time-dependent propensity scores.

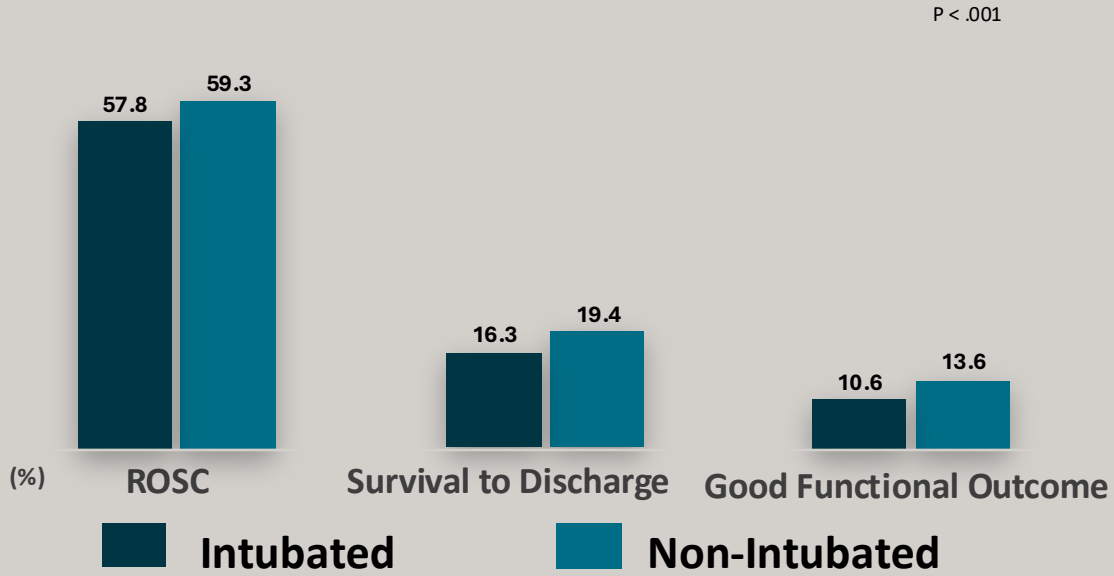
# Association Between Tracheal Intubation During Adult In-Hospital Cardiac Arrest and Survival

Lars W. Andersen, MD, MPH, American Heart Association's Get With The Guidelines-Resuscitation Investigators

## RESULTS

**108,079 patients IHCA without ET before arrest**

- **Survival lower in intubated patients** (RR = 0.84, P < .001).
- **ROSC lower in intubated** (RR = 0.97, P < .001).
- **Good functional outcome lower in intubated** (RR = 0.78, P < .001).
- **No subgroups showed improved outcomes with intubation.**




## CONCLUSIONS

Early tracheal intubation in IHCA linked to decreased survival. Findings do not support intubation during the first 15 minutes of adult IHCA.

# Retrospective cohort study of hospital variation in airway management during in-hospital cardiac arrest and the association with patient survival:

## Insights from Get With The Guidelines-Resuscitation

Steven M. Bradley[1*], Yunshu Zhou[2], Satya Krishna Ramachandran[3], Milo Engoren[4], Michael Donnino[3] and Saket Girotra[2]

**IMPORTANCE**

The best approach to airway management during IHCA is still unknown.

Analyze hospital-level variations in endotracheal intubation during CPR for IHCA and its impact on survival.

**DESIGN & PARTICIPANTS**

- Retrospective cohort study (2000-2016) at Get With The Guidelines Resuscitation hospitals.
- Hospitals categorized into quartiles based on intubation rates during CPR.
- Risk-adjusted models assessed the link between intubation rates and survival.

# Retrospective cohort study of hospital variation in airway management during in-hospital cardiac arrest and the association with patient survival:

## Insights from Get With The Guidelines-Resuscitation

Steven M. Bradley[1*], Yunshu Zhou[2], Satya Krishna Ramachandran[3], Milo Engoren[4], Michael Donnino[3] and Saket Girotra[2]

**RESULTS**

- 155,252 IHCA patients across 656 hospitals; 69.7% received intubation, with 24.8% survival to discharge.
- Inverse association between hospital intubation rate and survival (highest vs. lowest quartile, OR = 0.81; 95% CI, 0.74-0.90; P < .001).
- Association impacted by pre-arrest respiratory failure, with lower survival in high-intubation hospitals only in patients without prior respiratory failure.

**CONCLUSIONS**

- **Intubation rates during CPR vary widely across hospitals and are inversely linked to survival in IHCA, especially in patients without prior respiratory failure.**
- **Identifying optimal airway management strategies may improve IHCA outcomes.**

# A Question for Consideration:

If ventilation is critical for neurological survival during CPR and intubation ensures proper ventilation, why are outcomes poorer when intubation is performed during IHCA?

# The Ventor Airway System

## Enhancing Resuscitation Effectiveness

A new investigational airway and ventilation device designed to improve oxygen delivery during CPR.

## Easy Insertion and Synchronization

Easy to insert and designed to synchronize with chest compressions.

# VENTOR

# Device Demo and Discussion After Presentation

# Ventor Preclinical Testing Results:

## Swine Resuscitation Model: Crossover Study

## Pivotal Randomized Controlled Animal Study: Result Summary

# Swine Resuscitation Model Details:

**Animals:**

Healthy Miniature Yorkshire Swine

**Measurements:**

- **Coronary Perfusion Pressure (CPP):** Measured using Millar Pressure Transducers in the aorta and right atrium
- **Carotid Blood Flow Velocity (CF):** Measured using Doppler flow probes placed over carotid vessels

**Procedure:**

- Cardiac arrest induced, with no CPR for several minutes to simulate downtime
- Mechanical chest compressions initiated, gradually increasing force to minimize rib trauma

# Crossover Swine Study Design and Results

**Ventilation Methods:**

- Ventor Airway and Ventilation vs. Endotracheal Intubation with AHA-guideline ventilation
- Alternated every 5 minutes over a total of 20 minutes (two treatments per method)

**Drugs:**

- No intra-arrest drugs were administered to isolate ventilation effects

**Arterial Blood Gases (ABGs):**

- Baseline (BL) ABGs collected before cardiac arrest
- ABGs sampled at the **end of each 5-minute treatment**

**Perfusion Pressures:**

- Aortic and coronary pressures calculated and compared between groups

**Cerebral Flow:**

- Recorded and averaged over the last 2 minutes of each 5-minute treatment

# The animal data is not available on the public domain.

To request access to the animal study results, please contact the PI.

# VENTOR Study Design

**Inclusion Criteria**

**Exclusion Criteria**

**Study Conduct**

**Safety Observations**

**Effectiveness Observations**

**Study Schema**

# Inclusion Criteria

1. Adults aged 18-75 years, inclusive

2. IHCA (non-traumatic) **where CODE team responds**

3. At least 4 feet in height

# Exclusion Criteria by Category

| | | | | |
|---|---|---|---|---|
| Do not qualify for CPR | Valid DNAR or study opt-out bracelet (including previous enrollment bracelet) | Obvious signs of irreversible death | | |
| Common for Airways | Known upper airway foreign body or mass | Lower airway obstruction | Dental gap of < 2 cm | Ingested caustic substances |
| Common for Clinical Studies | Known vulnerable subject (e.g.: prisoner, pregnancy, terminal illness, dementia | LAR or Family member objects to enrollment | History of medical, surgical, or other conditions that, in the opinion of the investigator, would limit study participation | |
| Unique to the VENTOR Study | Endotracheal Tube already in place | Blunt, penetrating, or burn-related injury, drowning, or electrocution | Medicine Admitting Note's medical history is incomplete or has only been completed by an emergency physician. | |
| | Known esophageal disease or facial/perforating neck trauma defined as study candidates with the following medical history: | | | |

# Study Conduct

### Enrollment

- Up to 25 IHCA subjects, staged in 5-subject increments with reporting to FDA

### Procedure

- Ventor Airway System used exclusively by certified and trained professionals

### Standard of Care

- All other resuscitation follows ACLS guidelines (compressions, defibrillation, drugs)

### Study Measures

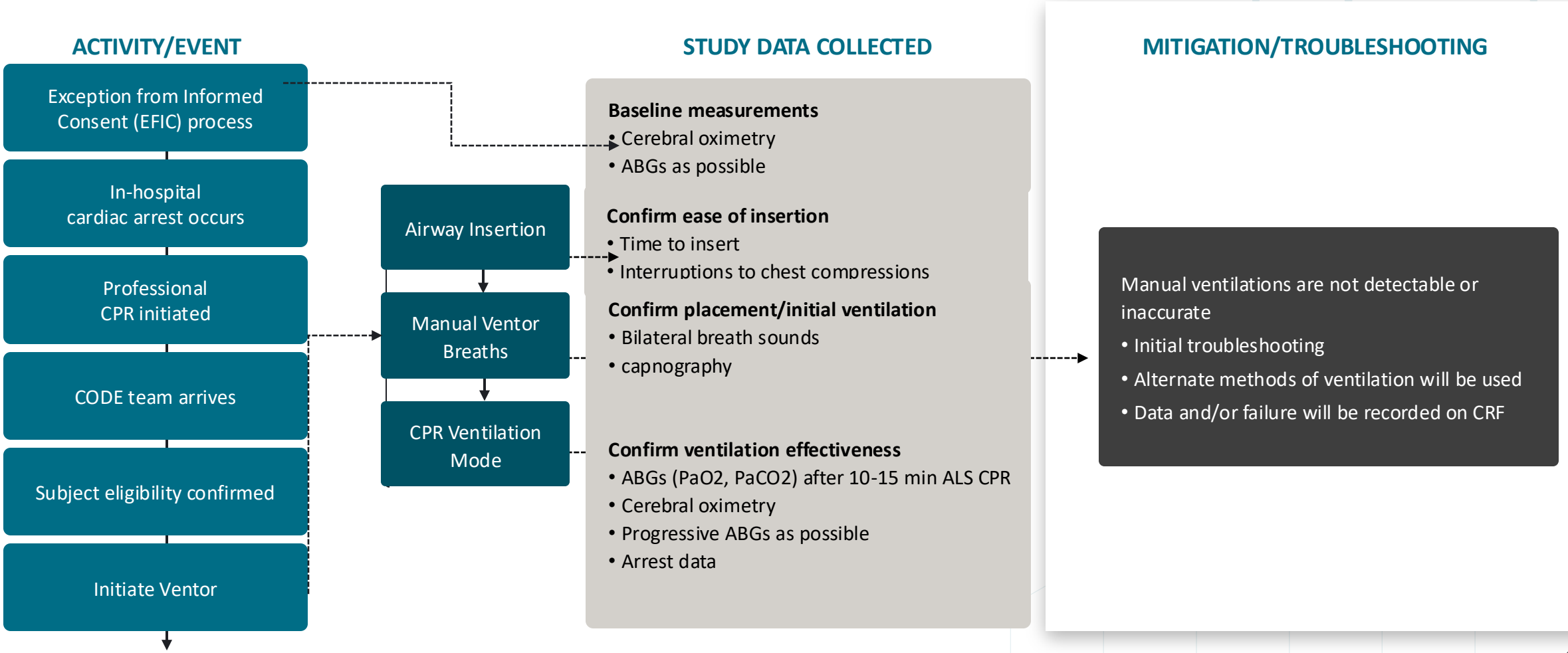
- Focus: Initial safety and effectiveness of Ventor Airway System
- Assessed on ventilation and oxygenation performance during CPR by evaluating ABGs and Cerebral Oximetry

### Study Timeline

- Participation from Ventor Airway use through hospital course
- Ends at 3-month follow-up or upon death

# Study Schema

Device Use Activity, Data Collection, and Mitigation Plans



# Safety Observations

## SAE Analysis:

- Assess type, frequency, and device/procedure relationship for all SAEs. Unrelated SAEs assessed separately.

## Esophageal-Related:

- Track any esophageal trauma or GI issues linked to the Ventor Airway System (per CEC adjudication) at:
  - Initial device use
  - 2-day evaluation (questionnaire or esophagoscopic)
  - 3-month evaluation (questionnaire or esophagoscopic)
  - Any time during enrollment

## Asphyxia-Related:

- Analyze any asphyxia physiology attributed to the Ventor Airway System (per CEC adjudication).

# Effectiveness Observations

## Ease of airway insertion

- Number of attempts
- Duration of insertion process
- Duration of interruptions to chest compressions

## Patency of Ventor Airway

- Accuracy of location identification and monitoring
- Ability to properly pressurize lungs
- Incidences of regurgitation and/or aspiration

## CPR mode ventilation effect on:

- Intra-arrest ABG (including but not limited to $PaO_2$ and $PaCO_2$)
- Cerebral oximetry
- $EtCO_2$

## Effect of the Ventor Airway System on:

- ROSC rate
- Time of unassisted breathing
- Survival rate to 2 days, discharge (if before 3 month evaluation), and 3 months.

## Neurological assessment:

- mRS score at 2 days and at 3 months post-event

# Risk Associated with the VENTOR Study

**General Clinical Research Risks**

**Operational Risks**

**Study-Related Risks**

**Device-Specific Risks**

# Device-Specific Risks and Mitigations

| Risk Category | Details | Mitigation(s) |
|---|---|---|
| **Airway Misidentification** | Potential for incorrect determination of trachea or esophagus | Extensive pre-clinical testing, continuous monitoring and alarms are necessary to mitigate this risk. |
| **Esophageal Trauma** | The use of negative pressure to seal the esophagus could cause tissue trauma, particularly in patients with pre-existing esophageal conditions | Exclusion of patients with known esophageal disease and limiting device use to <1 hour |
| **Ventilation Issues** | Potential for hypoventilation or hyperventilation, particularly in real-world emergency settings | Automated synchronization with chest compressions aims to reduce these risks. |
| **Mechanical Failures** | Issues like incorrect ventilation rates, battery failure, or environmental damage | Alternative ventilation equipment available and sponsor proctoring. |
| **User-Related Issues** | Improper setup or operation of the device and difficulty with airway insertion | Comprehensive training and user manuals aim and sponsor proctoring . |
| **Unknown Risk:** | There is always the concern of unknown risk when studying a novel device | Controlled study environment and site |

# Operational Risks

**Difficulty in Airway Insertion:**

Insertion challenges leading to delays in establishing an airway. The device's design aims to reduce these difficulties, supported by comprehensive user training and limitations on insertion attempts.

**Aspiration and Infection:**

High likelihood of aspiration due to reduced gag reflex and increased gastric distension during CPR. The Ventor includes suction capabilities, but limitations exist for subglottic suctioning when placed in the esophagus.

**Improper Ventilation Pressures:**

Risks of barotrauma and gas trapping. The device includes pressure-sensing alarms and mechanical relief valves to mitigate these risks.

# Potential VENTOR Benefits

**Enhanced Oxygenation and Survival**

**Ease of Use and Rapid Airway Management**

**Consistent and Automated Ventilation**

**Contribution to Medical Knowledge**

# Consenting during emergency research

**Specific Federal regulations allow for Exception From Informed Consent (EFIC) for emergency research**

**EFIC is only allowed when:**

- The condition under study is life threatening
- Existing treatment are unproven or inadequate
- There is potential benefit for patients
- Informed consent cannot be obtained.

# EFIC Process

**Community consultation (why we are here)**

**Public disclosure before and after study**

**Oversight during study**

# Can patients opt-out of the study?

- Anyone in the community can opt-out of the study before or during enrollment.
- If a family member or representative is present during subject screening, they will be **informed** of enrollment and can object to prevent the subject's participation.
- If they are not available, eligible patients will be started in study without consent.
- Patients, family members, and representatives are told about the study as soon as possible and asked if they want the patient (or themselves) to continue in the study.

# Discussion

**If you have any concerns or questions, please call us or contact us.**

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# Thank you.

- Please complete this **anonymous** feedback survey by pressing on this link from the chat- box or the QR code provided.

https://stonybrookuniversity.co1.qualtrics.com/jfe/form/SV_3jwhl0nGa2iAG8K