Dr. Lisa Wolfe is currently an Associate Professor in Medicine-Pulmonary and Neurology in the Northwestern University Feinberg School of Medicine. She is a member of the Neurology Faculty in both Sleep and Neuromuscular Medicine. She also works as the Director of Respiratory Care at the Rehabilitation Institute of Chicago, and is a pulmonary consultant to the Les Turner ALS foundation, the Sleep Medicine program of the Lurie Children’s Hospital, and the Muscular Dystrophy Association of Chicago.

Dr. Wolfe obtained her Medical Degree from The Ohio State University, and trained in Internal Medicine at Northwestern University and then stayed on to complete fellowship training in Pulmonary, Critical Care, and Sleep Medicine. She has remained at Northwestern as faculty and developed a special interest in home based ventilation focusing particularly on the needs of those with neuromuscular disorders. Her current research focus on new trends in home ventilation including advanced modes such as servo-ventilation and volume assured pressure support as well as the use of alternative devices such as diaphragmatic pacing.

**OBJECTIVES:**

Participants should be better able to:

1. Consider the options available for advanced speech and communications for those patients with respiratory impairment in the setting of neuromuscular disease.

2. Establish treatment options utilizing appropriate new modes of non invasive ventilation for those patients with respiratory impairment in the setting of neuromuscular disease.

3. Develop broad range of inputs to best evaluate the need for mechanical ventilation with mask for those patients with respiratory impairment in the setting of neuromuscular disease.

4. Utilize non invasive ventilation download applications to encourage/ support self care for those patients with respiratory impairment in the setting of neuromuscular disease.

5. Recognize the need for multiple modality airway clearance plans for patients with respiratory impairment in the setting of neuromuscular disease.
Dr. Wolfe has received research grants from ResMed, Synapse Biomedical, Hill Rom, and Respironics, but these do not create a conflict related to the following presentation.
COI

• No conflicts related to the topic of this talk
• No of label uses will be discussed in this talk
• Conflicts with research studies and consulting including:
  – ResMed
  – Philips Respironics
  – Synapse Biomedical
  – Hill- Rom

Neuromuscular Disease:
The Role of Technology

Technology for the NMD patient

• Airway clearance technologies
  – New cough assist technologies
  – New vibration based technologies
• Communication technologies
  – Leak speech
  – Voice banking
  – Gaze Device
• New/ Old NIV device technologies
  – Biphasic cuirass ventilation (BCV)
• New NIV Devices
  – ST devices
  – VAPS
  – ASV
• Device monitoring technologies

The case for full mechanical ventilation with non-invasive interface

• Battery
  – Safety
  – Portability
• Sip Ventilation
  – CO2
  – Mortality
• Breath stacking
  – LVR
  – Cough
  – Swallow
  – Communication
• 24 hour NIV
• Cons
Goals of Respiratory Care in Neuromuscular Disorders

<table>
<thead>
<tr>
<th>Areas of weakness/ challenge</th>
<th>Weakness related respiratory complications</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Glottic weakness</td>
<td>• Secretion clearance</td>
</tr>
<tr>
<td>• Swallow impairment</td>
<td>– Nasal</td>
</tr>
<tr>
<td>• Diaphragmatic</td>
<td>– Chest</td>
</tr>
<tr>
<td>– Weakness</td>
<td>– Oral</td>
</tr>
<tr>
<td>– Control of ventilation</td>
<td></td>
</tr>
<tr>
<td>• Accessory muscle drop out</td>
<td>• Atelectasis</td>
</tr>
<tr>
<td>– Inspiratory muscles</td>
<td>– Lung volume recruitment</td>
</tr>
<tr>
<td>– Expiratory muscles</td>
<td>– Micro aspiration</td>
</tr>
<tr>
<td>• Core muscle weakness</td>
<td>• Communication failure</td>
</tr>
<tr>
<td>• Musculoskeletal</td>
<td>• Hypoventilation</td>
</tr>
<tr>
<td>– Scoliosis</td>
<td></td>
</tr>
<tr>
<td>– Seating/ positioning</td>
<td></td>
</tr>
<tr>
<td>– Chest wall</td>
<td></td>
</tr>
</tbody>
</table>

Question 1

• For patients with neuromuscular disorders an airway clearance plan is helpful. All of the above are important outcomes of regular airway clearance but which is the most important:
  1. Improve voice amplification
  2. Reduction in work of breathing
  3. Mitigate risk of pneumonia
  4. Palliate fatigue with eating
QUESTION 1
For patients with neuromuscular disorders an airway clearance plan is helpful. All of the above are important outcomes of regular airway clearance but which is the most important:

1. Improve voice amplification
2. Reduction in work of breathing
3. Mitigate risk of pneumonia
4. Palliate fatigue with eating

Airway Clearance

Device Goals
- Vibration
- Secretion Consistency:
  - Drying vs Waterlike
- Lung Volume Recruitment
- Expiratory Support

Device Options
- Vibration
  - Airway Vibration – at the lips
  - Chest wall Vibration
- Drying vs Wetting
  - Nebulization solution
  - Humidity
  - Saliva control
- Lung Volume Recruitment
  - Ambu bag breath stacking
  - Mechanical “cough” assist
  - Breath stacking on vent
Airway Clearance: Vibration

**Airway Vibration**

- Pulm Reha programs have used devices where the vibrations require significant patient effort.
- Concerns in the setting of NMD:
  - Insufficient flow
  - Weak "embouchure"
- Devices:
  - PEP: Flutter™, Acapella™, Aerobika™, and Cornet™
  - PEP + Acoustic:
    - Vibralung™

**Chest Wall Vibrations**

- High Frequency Chestwall Oscillation (HFCWO) has been most commonly used in the setting of bronchiectasis.
- Concerns in the setting of NMD:
  - Hypersecretion
  - Sialorrhea
  - Swallow issues with micro aspiration
- Advantages for those with:
  - Cognitive impairment
  - Bulbar dysfunction
- Devices:
  - Therapy Vest™
  - AffloVest

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**Electro-Mechanical-Acoustical Airway Clearance:**

Promotes muckinesis by vibrating the column of gas in the airways with sounds at different frequencies. It is unclear if this technology will have a role in NMD but there is a promise which other devices in the category don't have. Patient generated flow is not needed.

**Airway Clearance: Vibration**

**Chest Wall Vibrations**

![Graph showing medical costs per member per month (PMPM) for various categories.](image)

- Medical costs per member per month (PMPM)
  - Total cost ↓ by $1,111 (12.4%) (p=0.035)
  - Inpatient admission costs ↓ by $1,812 (p=0.003)
  - Pneumonia costs ↓ by $326 (p=0.031)

**Data** (N=426; 2007-11) obtained from two large databases of commercial insurance claims. Patient with NMD codes and started on HFCWO

**Outcomes** included total medical costs per member per month, pharmacy costs per member per month, inpatient hospitalizations, emergency room visits, and claims for pulmonary diagnoses or pneumonia.

*Lechtzin NL; Annals of the American Thoracic Society InPress; 2016*

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**Airway Clearance: Secretion Consistency**

**Thick**

- Causes
  - Dehydration
  - Over drying – medications
    - Anticholinergics
  - Mouth breathing

- Treatments
  - Saline nebs
  - Humidifiers
  - Papaya/ Pineapple/ Red grape juice

**Waterlike**

- Causes
  - Medications
    - Mestinon
  - Immobile tongue

- Treatments

**Dry palate and simultaneous drooling due to a weak tongue**

---

*Sublingual gland*  
*Submandibular gland*
Airway Clearance: Secretion Consistency

Thick  Waterlike

New therapies to reduce saliva

- Botox
- Ligation
- Suction
- Ablation
- Radiation
- Future drug: Tropicamid Films

Airway Clearance: Secretion Consistency

Thick  Waterlike

New therapies to reduce saliva

- Botox - The most effective way of treating sialorhea

Lakraj, AA Toxins 2013, 5, 1010-1031

- Ligation - Complications:
  - Airway obstruction
  - Respiratory insufficiency
  - Sialodendritis
  - Persistent fistula
  - Floor-of-mouth cyst
  - Ranulas


- Suction
- No Bite V

- Deep suctioning options
- Good for Oral Care
Airway Clearance: 
Secretion Consistency

Thick Waterlike

New therapies to reduce saliva

<table>
<thead>
<tr>
<th>Method</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ablation</td>
<td>- Alcohol ablation of the submandibular, sublingual, and parotid glands</td>
</tr>
<tr>
<td></td>
<td>- Requires intubation</td>
</tr>
<tr>
<td></td>
<td>- Complications include facial nerve injuries</td>
</tr>
<tr>
<td></td>
<td>- No publications</td>
</tr>
<tr>
<td>Radiation</td>
<td>- 50% response treated with photons</td>
</tr>
<tr>
<td></td>
<td>- 87.5% response treated with electrons</td>
</tr>
<tr>
<td></td>
<td>- Positive responses were more common with a high total dose (≥ 16 Gy, 78.5%) than a low total dose (&lt; 16 Gy, 33%; P = 0.07)</td>
</tr>
<tr>
<td>Future drug</td>
<td>Tropicamide Films</td>
</tr>
</tbody>
</table>


Airway Clearance: 
Lung Volume Recruitment

Ambu bag with breath stacking

- Significantly positive effect on:
  - FVC for up to 15 min following treatment
  - PCF during unassisted coughing at 30 min following treatment

- Improves Speech outcomes
  - Vocal volume
  - Swallow

LVR slows loss of FVC

2) STUART CLEARY Amyotrophic Lateral Sclerosis and Frontotemporal Degeneration, 2013; 14: 111–115
Airway Clearance: Lung Volume Recruitment

**Mechanical Cough Assist**

- Expired volume increases (2x).
- MIP/MEP/PEF increases
- End-tidal carbon dioxide pressure decrease significantly

Brigitte Fauroux CHEST 2008; 133:161–168

**GOALS:**
1) Lung Volume Recruitment
2) Chest wall ROM
3) Clear Nose
4) Clear Chest Secretions

---

Airway Clearance: Lung Volume Recruitment

**Breath Stacking**

- Use of sip ventilation
  - Breath stacking
  - Augments cough
  - Adds patient control – it can be done unassisted

Airway Clearance: Lung Volume Recruitment

- No difference between the bulbar and the non-bulbar groups.
- Addition of an inspiratory technique was better.
- The in/exsufflator was not always the best tool.
- Coughing efforts can be dramatically improved with different tools, even in patients with very severe bulbar symptoms.

- Tailor cough improvement techniques to the individual

Question 2

- Speech and language pathologists should include respiratory therapists in “co-treats” for patients on ventilators. The answers below are all reasonable goals for these seasons, which is most important:
  1. Assess swallow performance with the tracheal balloon both inflated and deflated
  2. Assess secretion burden prior to trialing a speaking valve
  3. Adjust mechanical ventilation settings to allow for appropriate ventilation during leak speech
  4. Consider tracheostomy changes of both size and type to better facilitate speech.

[Image of box plots showing cough techniques and their effectiveness]
QUESTION 2

Speech and language pathologists should include respiratory therapists in “co-treats” for patients on ventilators. The answers below are all reasonable goals for these seasons, which is most important:

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3. Adjust mechanical ventilation settings to allow for appropriate ventilation during leak speech.
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Communication: Autonomy

- **Autonomy** is a central value in Western medicine and medical ethics
- The ability to communicate = Autonomy
  - The ability to direct daily self care
  - The ability to make health care choices
  - The ability to lead a life of self-realisation

- Leak speech
- Voice banking
- Gaze Device

Communication: Leak Speech

• What’s new
  – Home vents with passive circuits
  – Home vents with VERY sensitive leak compensators

• What does this cause
  – More alarms
  – Compensation can cause severe alkalosis

Hoit, JD Journal of Speech and Hearing Research, Volume 37, 53-63, February 1994

Grossbach, I. Crit Care Nurse 2011, 31:46-60

Communication: Voice Banking

• Why is this a discussion for pulmonologists?
  – It is part of the discussion of disease progression for all progressive neurologic disorders
    • ALS/ MSA/ etc
      – H&N CA

modeltalker.org
Communication: Gaze Devices

- Can be used as an interface between the pt on a vent and:
  - Phone
  - Text
  - Internet
    - Shopping
    - E-Mail
    - Chat rooms
- Use in the ICU


Question 3

- New modes of non – invasive ventilation are listed below. Which one is these not appropriate for those with neuromuscular disease:
  1. Servo- Ventilation
  2. Volume Assured Pressure Support
  3. VPAP auto / BiPAP auto
  4. Pressure Control
QUESTION 3
New modes of non – invasive ventilation are listed below. Which one is these not appropriate for those with neuromuscular disease:

1. Servo- Ventilation
2. Volume Assured Pressure Support
3. VPAP auto / BiPAP auto
4. Pressure Control

Ventilation: what’s old is new again

• Biphasic Non-Invasive Cuirass Ventilator (BCV)
  – Negative pressure ventilation
  – Limited data (esp. in adults)
  – Can now be used for both NIV and airway clearance
  – Problems
    • Shell fitting
    • Synchrony
    • Healthcare provider discomfort
    • Access to device
Ventilation: what’s old is new again

- Traditional NIV devices with a back up rate have a new life:
  - Fixed pressure modes:
    - PC
    - ST
  - Auto Modes
    - Volume assured pressure support (VAPS) devices
    - Servo-Ventilation (SV) devices

- Remote Monitoring

- Is there a role for the sleep lab?

ALS: The extension of inspiratory time

- Ti Extension
  - Improved VT
  - Reduced RR
  - Reduced WOB
  - More likely to recruit atelectasis and reduce issues with v/q

- What does this mean for mode used?
  - Spontaneous- Timed (ST) – to assure Ti time with each breath you would need to use ResMed device.
  - Pressure – Control (PC) – to assure Ti time with each breath you could use a Respironics device

Ventilation – Volume Assured Pressure Support (VAPS)

**First Generation VAPS**

- VAPS is an ADD–ON
  - Choose mode first – S/ ST or PC
  - The target Tidal Volume is chosen
    - Usually about 8 cc/ kg IDBwt
    - The only option to achieve the goal is to increase PS
      - Slow increase based on averaging VT’s
  - Back up rate is fixed
- There is an option for “Learned Targets”
  - Is the device “learning” the best thing?

**Second Generation VAPS**

- VAPS is a UNIQUE mode
  - AVAPS-AE
    - The mode is not adjustable – it is ST (Philips)
    - Back up rate
      - Option for the device to "auto" RR by targeting the RR of the first 15 breaths
        - Rate can be fixed as well
    - Tidal Volume
      - Same targeting as AVAPS – to treat hypoventilation
    - EPAP
      - Auto EPAP
        - Set to target UPPER AIRWAY obstruction
  - iVAPS
    - The mode is not adjustable – it is ST (ResMed)
    - Target - Uses a unique Calculator for Alveolar Ventilation (Va)
    - Back up rate
      - Is a target not a fixed value
      - is a factor in the Va calculation

**Pitfalls**

- Avoid starting to low
- Avoid setting your ceiling to low
- Avoid mask leaks
  - Invalidates targeting
- Is there a role for the sleep lab?
Ventilation –
Volume Assured Pressure Support (VAPS)

Modes of Ventilation – IVAPS

- Optimize ventilation with an algorithm that targets Alveolar Ventilation to reduce PCO2
  - Adjust for height
  - Assure stable respiratory rate
  - Targeting Alveolar Volume
    - How to estimate:
      - From the lab system
      - From the IVAPS device
      - From eth on line calculator

Alveolar Partial Pressures and Ventilation

IVAPS Calculator

C:\Documents and Settings\sleepmd\Local Settings\Temp\Temporary Directory 1 for ResMed%20IAP%20Settings%20Calculator_RevisedFinalDraft.mht

- Input the height
- Set the back up rate a smidge higher then you think and lower then spontaneous
- Then pick either a vt/kg ideal body weight OR specific vt goal
- Then hit calculate to get the Alveolar volume (Va) to input on eth device settings
Home Based NIPPV in NMD:

Is VAPS a substitute?

- Mixed group of NMD patients
- VAPS seems to have made everything worse???

This study suggests that compliance may be better with VAPS devices.

- In PAP naive pt’s
  - Obstructive and Restrictive disease
- Followed for one month
- VAPS (5:40 vs 4:20)
  - showed better compliance
  - Reduction in variability of compliance

Kelly, JL Respirology (2014) 19, 596–603

**Ventilation - ASV**

- **PS** - Augments IPAP when breathing amplitude is reduced and ensures sufficient respiration when respiratory effort is absent (variable PS)
- **EPAP** – Measures upper airway patency and adjusts as needed (fixed or variable EPAP)
- **Rate** - ensures sufficient respiration when respiratory effort is absent (fixed or variable/auto RR)

Although algorithms employed by different ASV devices vary slightly, the principle of treatment is the same: back-up rate ventilation with adaptive pressure support.
Ventilation - ASV

Loop Gain

Ventilation: what’s old is new again
IVAPS vs ASV

**IVAPS**
- **AUGMENTS** minute ventilation so that the patient’s total ventilation is INCREASED to prevent HYPOVENTILATION in the setting of:
  - Can’t breath:
    - NMD disorders
  - Won’t breath:
    - Genetic
      - CCHS
    - CNS disorders
      - Bilateral Strokes
      - Brain stem tumors
      - Chiari
    - Obesity Hypoventilation (?– US vs Rest of the World)

**ASV**
- **STABILIZES** ventilation so that the patient’s total ventilation is DECREASED by buffering apnea to prevent HYPERVENTILATION:
  - Loop Gain Instability
    - CHF/ AFib
    - Narcotics
    - Not an issue in NMD???
      - NOT ANY MORE
        - Spinal Cord Injury
The Case of C-SCI teaches us the following:

1) Absolute CO2 levels cannot predict control of breathing or stability of breathing

2) C-SCI therapy remains an inadequately explored situation.

Ventilation - Monitoring

- Goals to monitoring
  - Regulation
  - Physician management
  - Patient self management

Ventilation – Monitoring/ Regulation

- Compliance is not a standard for any other therapy:
  - EX: Mean adherence to ICS is 33.8%
- Compliance continues to improve over time for patients with NMD
  - Very different then for pt’s with OSA for whom even NIGHT 1 has been shown to predict long term compliance

This is a retrospective sample of 88 ALS pt’s.

Ventilation – Monitoring/ Self management

- Goals to monitoring
  - In the setting of OSA overall health literacy level influences:
    - Compliance
    - Cardiac outcomes
  - No data in the area of NMD

Li JJ; Sleep. 37(3):571-8, 2014 Mar.
Ventilation – Monitoring/ MD Management

• Goals to monitoring
  – Physician management
    • Mask fitting
    • Efficacy of therapy
  – Are there still question?
    • Are we responsible for data that is possible to obtain but has not been reviewed?
    • No data on the number of physicians that
      – Look at data
      – Use data
        » What parts of the data?
    • Physician time and resources to evaluate the device and data is not reimbursed.

The software in devices is not:
  – Peer reviewed
  – Paid for by insurance
  – Regulated as a part of the device

Question 4

• There is a huge concern in regard to the escalating use of full mechanical ventilator with mask interface. Neuromuscular patients are most likely to need these devices because off all of the reasons below. Which of these indications has been best accepted by CMS to date:
  1. Need for sip ventilation to address dyspnea
  2. Provide a mechanism to independently breath stack and cough during the day
  3. The presence of persistent elevated PaCO2
  4. Support effective vocalization
QUESTION 4
There is a huge concern in regard to the escalating use of full mechanical ventilator with mask interface. Neuromuscular patients are most likely to need these devices because off all of the reasons below. Which of these indications has been best accepted by CMS to date:

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2. Provide a mechanism to independently breath stack and cough during the day
3. The presence of persistent elevated PaCO2
4. Support effective vocalization

One last question......

The case for mechanical vent. with non-invasive interface

- New CD on the EO464 reduction in coverage
- The new standard will be to use a RAD if the condition is "not life-threatening conditions where interruption of respiratory support would quickly lead to serious harm or death. These policies (for RADS) describe clinical conditions that require intermittent and relatively short durations of respiratory support."

https://www.cms.gov/ LCDId=33800
What are the factors driving this change?

- Challenges with the current criterion needed to obtain Bi-Level PAP (BPAP) device.
  - In NMD – need is only for either FVC/MIP/PaCO2 or Over night pulse ox.
  - BUT in other conditions obtaining BPAP may require PSG, NC oxygen trial, etc.
- Advances in technology that have made the use of mechanical ventilator with non-invasive interface MUCH easier
  - Access to passive circuits, which allow for the use of vented masks.
  - Smaller more portable devices
  - Pre – made kits to facilitate the hardware needed for mouth piece ventilation (MPV)
  - Devices that can be pre-programmed with multiple settings to facilitate day and night use.
  - Vents that can provide home monitoring and data downloads
- Pressure to reduce readmission rates in COPD and CHF

---

Home Ventilation to Reduce Rehospitalization in COPD

**Study Plan**

- Retrospective study (N=397)
  - Mostly Male and Caucasian
  - Complex medically (1/3 with CAD/HF/DM/Anxiety)
- Quality improvement programs
  - Barnes Healthcare Services (Valadsta, GA)
  - 2010-2014
- Program components
  - Pharmacist for med teaching
  - RT for
    - AVAPS- AE /NIV support
    - Home O2
    - Care Co-Ordination
      - Visits q30 d X 3 visit then q90 d
    - Stop smoking plans

**Study Results**

<table>
<thead>
<tr>
<th>COPD-related Admissions</th>
<th>Patients with admission in the year prior to program initiation (n [%])</th>
<th>Patients with admission in the year post program initiation (n [%])</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0 (0%)</td>
<td>348 (87.7%)</td>
</tr>
<tr>
<td>1</td>
<td>0 (0%)</td>
<td>40 (10.1%)</td>
</tr>
<tr>
<td>≥2</td>
<td>397 (100%)</td>
<td>9 (2.2%)</td>
</tr>
</tbody>
</table>

Coughlin S, Liang WE, Parthasarathy S. et al
The case for mechanical vent. with non-invasive interface

What does a mechanical ventilator have to offer?

- **Battery**
  - Safety
  - Portability
- **Sip Ventilation**
  - CO2
  - Mortality
- **Breath stacking**
  - LVR
  - Cough
  - Swallow
  - Communication
- **24 hour NIV**
- **Cons**
  - Cost
  - Humidity
  - Remote control
  - Sleep lab are not prepared

Refs:

The case for mechanical vent. with non-invasive interface

- Greater than 8 hours per night of use:
  - Need for portability and backup battery.
  - Further support that could be used with either mask or mouthpiece.
  - The use of portable ventilators with oral or nasal interfaces can prolong life and delay the need for tracheostomy.
- **Hypcapnea** - PaCO2 > 45 despite the use of adequate nocturnal NIV:
  - Need for daytime support mask or mouth piece
  - The use of daytime support in this group has been shown to stabilize vital capacity, and improve survival.
- Hypoxemia: If PaO2 is < 60 or O2 saturation is <92% while awake breathing room air.
  - The ATS standards for the care of those with Duchene muscular dystrophy support this recommendation
- Daytime dyspnea: A harbinger of the development of daytime hypercapnea
  - A resting modified Borg score of >2.5
  - Dyspnea with laying flat, performing transfers or engaging in physical therapy
    - Indication for mouthpiece ventilation, and is recommended in the Canadian Thoracic Society Guidelines.
The case for mechanical vent. with non-invasive interface

• Speech:
  – If speech is insufficient to allow for safety with telephone use, or productivity with a computer interface
    • Mouthpiece ventilation can be trialed.
• Swallow:
  – Fatigue with eating or microaspiration
    • Mouthpiece ventilation facilitated breath stacking can improve safety with eating and appetite.
• Very Low Lung Function:
  – FVC has reduced to below 30%
  – This finding predicts the development of daytime hypercapnea, which should be addressed with the initiation of daytime mouthpiece sip ventilation or mask based daytime ventilatory rest
• Nocturnal BPAP failure:
  – In those who fail to normalize oxygenation and/or ventilation during sleep with a BPAP at optimal settings.
  – Consider higher pressures to be delivered through a MV or alternative modes utilized such as volume ventilation.
  – This has been shown to improve survival, and reduces medical complications such as pneumonia.
• Alarms:
  – In young children, or those with very unstable medical conditions, robust alarm systems are needed and this may require the use of a MV.

The case for mechanical vent. with non-invasive interface

• The problem with this tug-of-war
• Whoever pulls to hard may take the other guy over the cliff.
• Compromise may be the only way to win.
Support / Thanks